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Congenital Anomalies and Hormonal Contraception/Contragestion: A Systematic Review

Ajiboye Moshood Olarewaju[1], Olayinka Olugbenga Olawole[2], Usman Haruna Usman[3] & Animashaun Saidat Yetunde[4]

[1]Department of Anatomy, Faculty of Basic Medical Sciences, Federal University of Health Sciences, Ila-Orangun, Nigeria

[2]Department of Anatomy, School of Basic Medical Sciences, Benjamin S. Carson (Snr.) College of Health and Medical Sciences, Babcock University, Ogun State, Nigeria

[3&4]Department of Anatomy, Faculty of Basic Medical Sciences, Federal University of Health Sciences, Ila-Orangun, Nigeria

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***Corresponding author:** Ajiboye Moshood Olarewaju

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Abstract **Review Article**

Background: Concerns remain regarding the potential teratogenic risks of hormonal contraceptives and contragestive agents (such as emergency contraception and mifepristone) when pregnancy occurs despite their use. This systematic review aimed to assess the risk of major congenital anomalies following early pregnancy exposure to these agents, including oral, injectable, implantable contraceptives, intrauterine devices (IUDs), and medical abortion drugs.

Method: A comprehensive search of PubMed, Embase, the Cochrane Library, and related databases through 2024 identified studies reporting congenital outcomes following in utero exposure to these agents. Eligible studies, regardless of design, provided data on exposure timing, type of anomaly, and effect estimates. The risk of bias was evaluated using Cochrane and Newcastle-Ottawa tools as appropriate.

Results: Findings consistently demonstrate no significant increase in major congenital malformations following first-trimester exposure to hormonal contraceptives or emergency contraceptive failure. Meta-analysis of prospective cohorts showed a pooled relative risk near unity (RR ≈1.00; 95% CI 0.83–1.19) for malformations after oral contraceptive use. Studies on levonorgestrel or ulipristal emergency contraception similarly showed no elevated risk. A recent systematic review also found no evidence that mifepristone exposure in early pregnancy results in teratogenesis. Isolated reports have suggested potential associations between injectable progestogens (e.g., depot medroxyprogesterone acetate) and limb anomalies or hypospadias, but the causative linkage is yet to be proof.

An exception is a recent single-center Chinese study reporting a higher rate of congenital malformations in pregnancies continuing with retained copper IUDs. However, this finding conflicts with broader evidence and requires replication.

Conclusion: current data do not support an increased risk of birth defects from early pregnancy exposure to hormonal contraception or contragestive therapies. Patients can be reassured of the high fetal safety profile of these methods, though careful management of inadvertent IUD pregnancies remains essential. Further large-scale surveillance could strengthen these conclusions.

Keywords: hormonal contraception, congenital anomalies, early pregnancy exposure, emergency contraception, teratogenic risk.

Introduction

Hormonal contraceptives and contragestive agents are widely utilized among women of reproductive age to prevent unintended pregnancies. In the United States, approximately 65–70% of sexually active women use some form of contraception, including combined oral contraceptives, progestin-only pills, injectable formulations, implants, intrauterine devices (IUDs), and transdermal or vaginal ring systems. In addition, contragestive methods such as emergency post-coital pills (e.g., levonorgestrel, ulipristal acetate) and anti-progesterone agents like mifepristone are commonly administered following unprotected sexual intercourse or contraceptive failure.

Given that these agents exert their pharmacological effects during or shortly after fertilization, concerns have been raised regarding their potential teratogenic impact should an early pregnancy continue after inadvertent exposure. This theoretical risk is particularly pertinent, as congenital anomalies (major structural or functional birth defects) affect approximately 1–3% of live births worldwide, representing a significant cause of neonatal morbidity, mortality, and long-term disability.

Although the majority of individual studies have not demonstrated a consistent association between maternal exposure to these agents and an elevated risk of congenital anomalies, some reports have suggested possible links to specific defects, such as limb or genitourinary malformations, especially in older case-control analyses. The current body of evidence remains fragmented and, in some cases, contradictory.

To address this gap, we conducted a systematic review adhering to Cochrane Collaboration standards. Our aim was to comprehensively evaluate and synthesize available data on the relationship between maternal exposure to hormonal contraceptives or contragestive therapies and the occurrence of congenital anomalies in offspring.

Methods

Search Strategy

A systematic literature search was performed across multiple electronic databases including PubMed/MEDLINE, Embase, the Cochrane Library, Web of Science, and relevant clinical trial registries from their inception through May 2024. The search strategy incorporated combinations of Medical Subject Headings (MeSH) and free-text terms related to hormonal contraception (e.g., “oral contraceptive,” “progestin,” “implant,” “intrauterine device”), contragestive agents (e.g., “emergency contraception,” “mifepristone,” “antiprogestin”), and congenital anomalies (e.g., “birth defect,” “congenital malformation,” “teratogenicity”). Boolean operators (AND/OR) were employed to ensure comprehensive coverage. Additionally, reference lists from pertinent systematic reviews and primary research articles were manually screened to identify further eligible studies (snowball sampling).

Example search strategy: ("oral contraceptive" OR "levonorgestrel" OR "intrauterine device" OR "mifepristone") AND ("congenital malformation" OR "birth defect" OR "teratogen" OR "limb defect").

Inclusion and Exclusion Criteria

Eligible studies were required to meet the following criteria:

- Human studies of any design (randomized controlled trials, cohort studies, case-control studies, case series) reporting congenital anomaly outcomes following maternal exposure to hormonal or device-based contraceptives or contragestive agents.

- Contragestive exposures included emergency contraceptives (levonorgestrel, ulipristal acetate), abortifacients (mifepristone), and instances where an intrauterine device (IUD) remained in situ after conception.
- Contraceptive exposures encompassed combined or progestin-only oral contraceptives, transdermal patches, vaginal rings, injectable formulations (e.g., depot medroxyprogesterone acetate), subdermal implants, and intrauterine devices (copper or levonorgestrel-releasing).
- Studies addressing pre-conception contraceptive discontinuation or failure prior to fertilization were excluded.
- Non-human (animal or in vitro) studies and mechanistic investigations were excluded.
- Only articles published in English and presenting original data on human pregnancy and neonatal outcomes were included.

Data Extraction

Two independent reviewers conducted the initial screening of titles and abstracts, followed by full-text assessment of potentially relevant studies. Data were extracted using a standardized form capturing key study characteristics (e.g., year of publication, study design, geographic location, sample size), exposure details (e.g., type and timing of contraceptive or contragestive use relative to conception), and reported outcomes (e.g., specific congenital anomalies, incidence rates, measures of association such as odds ratios or relative risks, 95% confidence intervals, and p-values). Discrepancies between reviewers were resolved through discussion and consensus.

Quality and Risk of Bias Assessment

The risk of bias for each included study was appraised based on study design. Randomized controlled trials (if identified) were evaluated using the Cochrane Risk of Bias 2 (RoB 2) tool, addressing domains such as randomization, allocation concealment, blinding, incomplete outcome data, and selective reporting. Observational studies (cohort and case-control designs) were assessed using the Newcastle-Ottawa Scale (NOS), examining selection of participants, comparability of study groups, and ascertainment of exposure or outcomes. Potential sources of heterogeneity such as recall bias in retrospective designs, small sample sizes, and inadequate control for confounding variables (e.g., maternal age, smoking status) were also noted. The overall strength of the evidence was categorized as low, moderate, or high, based on methodological quality and consistency of findings across studies.

Data Analysis

Where sufficient data were available, pooled estimates of congenital anomaly risk were calculated. However, due to heterogeneity in study designs, exposure definitions, and outcome measurements as well as the rarity of certain malformations quantitative synthesis (meta-analysis) was often unfeasible. Consequently, narrative synthesis was emphasized, with key effect sizes and 95% confidence intervals presented descriptively. Results were stratified by exposure type (hormonal contraceptives, emergency contraceptives, mifepristone, retained IUD) to facilitate comparison. Direct comparisons of congenital anomaly rates between exposed and unexposed groups were highlighted when reported.

Results

Literature Search

The systematic search identified several thousand records, of which 52 studies met the predefined inclusion criteria. These comprised population-based cohort studies, case-control studies, pregnancy exposure registries, and a limited number of randomized controlled trials (primarily focused on emergency contraception, with few pregnancies carried to term). Exposures assessed across these studies included combined and progestin-only oral contraceptives (OCPs), injectable formulations, subdermal implants, intrauterine devices (both copper and hormonal), emergency contraceptive pills (levonorgestrel, ulipristal acetate), and the antiprogestin

mifepristone. Reported outcomes ranged from overall rates of major congenital anomalies to specific defect categories such as cardiac, limb, neural tube, and genitourinary malformations.

Combined and Progestin-Only Oral Contraceptives

Overall Risk of Congenital Anomalies

The most robust body of evidence drawn from prospective cohort studies and meta-analyses—indicates no increased risk of major congenital malformations following preconception or early pregnancy exposure to OCPs. A seminal meta-analysis by Bracken (1990), incorporating 12 prospective studies, reported a pooled relative risk of 0.99 (95% CI: 0.83–1.19) for any congenital defect with first-trimester exposure. Subgroup analyses revealed no significant associations with cardiac defects (RR: 1.06, 95% CI: 0.72–1.56) or limb anomalies (RR: 1.04, 95% CI: 0.30–3.55).

Subsequent large-scale case-control studies and birth defect registries—including the National Birth Defects Prevention Study (USA)—consistently demonstrated no elevated risk of specific malformations, such as neural tube defects, cardiovascular anomalies, or limb abnormalities, following inadvertent early pregnancy use of OCPs.

Genital Anomalies and Hypospadias

Earlier case-control studies raised potential concerns regarding an association between maternal progestin use and male genital defects, particularly hypospadias. A notable European case-control study by Källén et al. (1992) reported an odds ratio of approximately 2.3 for maternal progestin exposure and isolated hypospadias. However, the authors acknowledged the possibility of recall bias and insufficient exposure data. Additionally, sporadic case reports and safety labeling information have cited this potential risk. Despite these early findings, contemporary systematic reviews and epidemiological data have not confirmed a teratogenic relationship. Consequently, while clinical guidelines recommend avoiding progestins during pregnancy as a precaution, there is insufficient evidence to substantiate a definitive risk of genital anomalies attributable to hormonal contraceptive use.

Limb Anomalies

Some early investigations suggested a possible association between progestin use and limb malformations. A retrospective cohort study from Thailand (Pardthaisong, 1988) observed a higher incidence of polydactyly and syndactyly among infants exposed to depot medroxyprogesterone acetate (DMPA) in utero compared to unexposed controls (4.9 vs. 1.7 per 1,000 births). However, these anomalies were rare, and subsequent research including data from the Norwegian Mother and Child Cohort Study (MoBa) has not corroborated this association. Regulatory summaries for DMPA acknowledge these isolated findings but interpret them as likely coincidental or attributable to bias, rather than as evidence of causation.

Genitourinary Anomalies

Few studies have explored the potential relationship between OCP use and genitourinary malformations. One U.S.-based birth registry analysis suggested a minor increase in urinary tract anomalies associated with periconceptional OCP exposure; however, methodological limitations undermine the reliability of this finding. Overall, the available literature does not support a significant impact of hormonal contraceptives on renal or urinary system development.

Implants and Injectables (Long-Acting Progestins)

Data concerning the teratogenic risks of long-acting progestins such as etonogestrel implants and levonorgestrel-releasing IUDs remain sparse. Existing studies have not identified specific patterns of congenital anomalies associated with these methods, and no consistent malformation signals have been observed. The isolated signal for limb defects linked to DMPA exposure, discussed above, has not been substantiated by subsequent research. Longitudinal follow-up of offspring exposed in

utero to DMPA indicates normal physical and neurodevelopmental outcomes. Consequently, while product labeling advises against the use of these agents during pregnancy as a precautionary measure, there is no credible evidence indicating a causative relationship with congenital defects.

Intrauterine Devices (Copper and Hormonal IUDs)

IUD Presence during Pregnancy

Pregnancy with an IUD in situ is rare due to the device's high contraceptive efficacy (>99%). However, when conception does occur with a retained IUD, studies consistently report increased risks of obstetric complications, including miscarriage, preterm birth, and infection. The potential teratogenic effects of such exposure remain less clear.

A comprehensive review by Brahmi et al. (2012) concluded that IUD presence during pregnancy does not significantly elevate the risk of congenital malformations, with concerns centered more on adverse pregnancy outcomes than fetal malformation.

Recent Findings on Malformations

A recent retrospective analysis from a single center in China ($n \approx 148$ pregnancies continuing beyond 28 weeks) reported a higher incidence of neonatal malformations in pregnancies complicated by retained copper IUDs compared to matched controls (10.8% vs. 1.4%, $p = 0.033$). The defects observed included cardiovascular anomalies and minor superficial malformations. While this result achieved statistical significance, it represents an outlier in the broader literature and may reflect chance, selection bias, or local confounding factors. Large-scale U.S. databases, such as the National Inpatient Sample, have not replicated these findings, and prior systematic reviews have not indicated a pattern of teratogenic risk associated with IUD exposure.

Conclusion on IUDs

There is no known biological mechanism by which IUDs acting locally within the uterine cavity would induce fetal malformations. Current evidence supports the conclusion that while retained IUDs elevate the risk of miscarriage and infection, they do not meaningfully increase the risk of congenital anomalies. The isolated Chinese report requires replication and confirmation. Clinical guidelines recommend prompt removal of an IUD if pregnancy is diagnosed, primarily to reduce obstetric complications rather than prevent malformations.

Emergency Contraception (Levonorgestrel and Ulipristal Acetate)

Pregnancies occurring despite the use of emergency contraception (EC) offer a unique opportunity to assess potential teratogenic risks associated with these agents. Two primary EC methods—levonorgestrel (LNG) and ulipristal acetate (UPA)—have been the subject of such evaluations.

Levonorgestrel-Based Emergency Contraception

A retrospective cohort study involving 36 women who conceived despite LNG-EC use demonstrated no increased risk of congenital malformations. Among the 25 liveborn infants evaluated, no major structural anomalies were detected, and neonatal growth parameters were within normal ranges. The incidence of pregnancy complications—including miscarriage, ectopic pregnancy, and preterm delivery—did not differ significantly from that of unexposed control groups. These findings are consistent with those of larger prospective studies, which similarly report no elevated risk of congenital anomalies associated with LNG-EC failure. Overall, the evidence does not suggest a teratogenic effect of levonorgestrel when conception occurs despite its use.

Ulipristal Acetate-Based Emergency Contraception

Prospective data from the German Embryotox registry evaluated outcomes in 95 pregnancies exposed to UPA, used either as EC or for fibroid treatment. Of the 37 live births with documented outcomes, no major congenital anomalies were

observed. The miscarriage rate (7 spontaneous abortions among 56 pregnancies) was within the expected range for the general population. A single retrospective case report described Beckwith-Wiedemann syndrome following UPA exposure; however, the relationship was deemed coincidental and unrelated to the drug. Collectively, these data provide preliminary reassurance regarding the safety of UPA during early pregnancy. Given that emergency contraceptive agents primarily function by preventing ovulation or implantation, embryos that successfully implant are unlikely to have been exposed to pharmacologically significant drug levels. Current clinical evidence supports the conclusion that UPA does not exert teratogenic effects.

Mifepristone (RU-486)

Mifepristone is widely used for medical termination of pregnancy, typically in combination with a prostaglandin analogue such as misoprostol. In rare cases where the regimen is not completed—such as omission of misoprostol—the pregnancy may continue, raising concerns about potential teratogenic effects.

Early animal studies suggested teratogenicity at high doses, prompting human investigations. A recent systematic review by Turner et al. (2024), which included studies published up to February 2024, comprehensively assessed fetal outcomes following mifepristone exposure. This analysis found no consistent evidence of increased congenital anomalies in exposed pregnancies. Isolated reports of malformations were typically attributed to confounding factors, including concomitant misoprostol administration or underlying chromosomal abnormalities. The reviewers concluded that human data do not support the classification of mifepristone as a teratogen.

While sporadic case reports, such as a potential association with Möbius syndrome following incomplete abortion, have raised theoretical concerns, no pattern or clustering of such defects has emerged in the literature. Current clinical guidelines state that inadvertent first-trimester exposure to mifepristone does not necessitate pregnancy termination on the basis of teratogenic risk alone. Thus, the continuation of pregnancies exposed to mifepristone is not considered to carry a substantially increased risk of congenital anomalies.

Summary of Key Statistical Findings

Due to heterogeneity in outcome measures and study designs, meta-analyses quantifying the overall teratogenic risk of hormonal contraceptive exposures remain limited. Table 1 summarizes findings from representative studies addressing the potential association between contraceptive exposures and congenital anomalies.

Table 1. Summary of Selected Studies Evaluating Hormonal Contraceptive and Emergency Contraceptive Exposure in Pregnancy and Congenital Anomalies

Study (Year)	Exposure/Design	Anomalies Assessed	Findings
Bracken et al. (1990) (Meta-analysis)	Combined OCs (Prospective)	Any malformation	Pooled RR = 0.99 (95% CI 0.83–1.19); no association observed
De Santis et al. (2005) (Cohort)	LNG-EC failure vs. control	Major congenital malformations	No increase in malformations (0/25 exposed vs. 0/80 controls)

Wagner et al. (2020) (Registry)	Ulipristal exposure (95 cases)	Birth defects, spontaneous abortions (SABs)	No birth defects; SAB rate within expected range
Brahmi et al. (2012) (Systematic Review)	IUD in situ vs. removed	Miscarriage, preterm birth (malformations not primary endpoint)	Retained IUD associated with higher miscarriage and preterm risk; removal improved outcomes
Chen & Zhao (2024) (Retrospective)	Copper IUD in situ ≥28 weeks vs. no IUD	Neonatal malformations	Elevated malformations (10.8% vs. 1.4%; p = 0.033) noted; interpretation cautious
Turner et al. (2024) (Systematic Review)	Mifepristone exposure (varied indications)	Fetal anomalies	No evidence supporting teratogenicity
DailyMed (2024) (Product labeling)	DMPA (Medroxyprogesterone) in pregnancy	Polydactyly, hypospadias	Observed increases in polydactyly/syndactyly and hypospadias; no definitive causal link established

Abbreviations: OC = oral contraceptive; LNG = levonorgestrel; EC = emergency contraception; IUD = intrauterine device; SR = systematic review; SAB = spontaneous abortion; DMPA = depot medroxyprogesterone acetate.

Discussion

This systematic review found no compelling evidence to suggest that modern hormonal contraceptives or contragestive agents increase the risk of congenital anomalies when exposure occurs around the time of conception. Across multiple studies—including large prospective cohorts, registries, and meta-analyses—the relative risk for major structural birth defects consistently approximates 1.0, indicating no difference compared to unexposed pregnancies.

High-quality evidence on oral contraceptive (OC) exposure demonstrates no elevation in overall malformation rates. Similarly, studies examining the outcomes of pregnancies that occurred despite the use of emergency contraception (levonorgestrel or ulipristal acetate) reveal no increase in the incidence of congenital anomalies compared to control populations. The single systematic review evaluating mifepristone exposure likewise did not reveal any teratogenic signal.

Occasional signals of potential risk reported in isolated studies—such as increased limb anomalies in depot medroxyprogesterone acetate (DMPA)-exposed pregnancies or hypospadias following progestogen exposure—have not been consistently replicated in larger or higher-quality analyses. For example, the reported increase in hypospadias and polysyndactyly with DMPA exposure, noted in product labeling, has not been confirmed by subsequent epidemiological research and is regarded by regulatory authorities as likely attributable to chance.

No professional health body has classified any hormonal contraceptive or contragestive drug as a proven human teratogen. Current clinical guidelines and expert reviews continue to assure healthcare providers and patients that inadvertent exposure to these agents during early pregnancy does not pose an established risk for birth defects.

A potentially concerning outlier was identified in a recent Chinese retrospective study reporting a

significantly higher rate of congenital malformations among infants of women with retained copper intrauterine devices (IUDs) during late pregnancy. This observation, however, stands in contrast to findings from broader systematic reviews, such as that by Brahmi et al., which did not demonstrate such an association. Methodological limitations—including single-center design, possible confounding factors such as delayed IUD removal or suboptimal prenatal care, and small sample size—warrant caution in interpreting these results. Until further corroborative studies are available, this finding should be viewed as hypothesis-generating rather than conclusive. Importantly, clinical concern over retained IUDs in pregnancy continues to focus on risks such as miscarriage, preterm labor, and infection rather than teratogenesis, and guidelines support prompt removal of IUDs to reduce these obstetric complications.

Strengths and Limitations

A major strength of this review lies in its comprehensive scope and adherence to Cochrane-standard systematic methods. The inclusion of the most recent data—including studies published in 2024—ensures that the synthesis reflects the latest available evidence. Furthermore, formal assessment of study quality strengthens the reliability of conclusions.

Nevertheless, several limitations must be acknowledged. The available literature remains dominated by observational studies, which are subject to potential biases, including recall bias, misclassification, and unmeasured confounding variables. Sample sizes for rare exposure scenarios—such as pregnancies continuing after failed mifepristone or ulipristal acetate use—remain small, reducing the precision of risk estimates. Additionally, the heterogeneity of outcome definitions across studies complicates quantitative synthesis. While most analyses focus on major structural malformations, data on more subtle or long-term outcomes, such as neurodevelopmental effects, are sparse and beyond the scope of this review. Residual confounding, such as differing health behaviors among contraceptive users, may also influence findings, though biological plausibility for teratogenic effects post-implantation remains low.

Implications for Practice and Research

For clinical practice, these findings are highly reassuring. Women who conceive while using oral contraceptives, transdermal patches, vaginal rings, implants, or injectable progestogens can be counseled that current evidence does not suggest an increased risk of major congenital anomalies. Standard prenatal care protocols remain appropriate, without the need for additional interventions or pregnancy terminations based solely on contraceptive exposure.

Similarly, patients who experience contraceptive failure with emergency methods (levonorgestrel or ulipristal acetate) can be reassured, as cohort studies consistently show no elevation in malformation rates. For pregnancies continuing after incomplete medical abortion with mifepristone and/or misoprostol, available data do not support the need for elective termination out of concern for teratogenesis.

Future research should focus on large-scale postmarketing surveillance using comprehensive population-based registries to monitor for rare or unexpected outcomes. Special attention may be warranted for copper IUD exposure in late pregnancy, given the recent signal, although confirmatory data are essential before altering practice recommendations. Investigations into potential neurodevelopmental outcomes and other subtler effects of early hormonal exposure could also enhance understanding, though the current evidence strongly suggests a negligible teratogenic risk.

Conclusion

In summary, the synthesis of current evidence indicates that exposure to hormonal contraceptives or contragestive agents at or near the time of conception does not result in a clinically meaningful increase in the risk of major congenital anomalies. Findings from

meta-analyses, prospective cohorts, and registry-based studies consistently demonstrate risk estimates approximating unity (risk ratio ~1.0). Recent data similarly exonerate emergency contraceptives (levonorgestrel, ulipristal) and mifepristone from teratogenic concern. Isolated signals of specific defects, such as limb anomalies or hypospadias associated with progestins, remain unconfirmed and are not supported by consistent epidemiological evidence.

A recent report of increased malformation rates with retained copper IUDs merits further investigation but remains an outlier in the broader evidence base. Overall, the totality of data supports the safety of modern contraceptive and contragestive pharmacotherapy with respect to fetal development. Clinicians can confidently reassure patients that unintentional conception during contraceptive use does not necessitate pregnancy termination or anticipatory concern regarding congenital malformations. Nonetheless, continued pharmacovigilance and high-quality research remain essential to detect any emerging safety signals.

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