

Vaginal Progesterone Pessaries(Cyclogest) For preterm birth prevention in singleton pregnancies

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What is vaginal progesterone?

Progesterone is a natural hormone made by the body throughout a woman's menstrual cycle. During pregnancy, it helps to support the growing uterus and prevent uterine contractions. In certain women who have a higher risk of preterm birth (before 37 weeks of pregnancy), treatment with vaginal progesterone pessaries may help to minimise the chance of this happening.

Our guideline is in line with NICE guidance and the World Health Organisation initiative: Saving Babies Lives Care Bundle (version 2), where we offer vaginal progesterone to women who have had:

- a previous preterm birth before 34 weeks or mid-trimester loss after 16 weeks of pregnancy
- no previous history of the above, but found to have a short cervix on transvaginal scan between 16 24 weeks

In certain cases, there are circumstances where an individualised care plan is developed and may include offering vaginal progesterone, such as:

- previous PPROM <34/40 (waters breaking early before labour)
- previous cervical cerclage (stitch)
- known uterine anatomical variant (unicornuate, bicornuate, septate)
- previous cervical surgery (LLETZ, trachelectomy, knife cone biopsy)
- previous delivery by caesarean section at full dilatation

How do I use it?

Natural progesterone is available in a pessary form which is inserted into the vagina every evening from the time your doctor advises it. This is usually between 16-20 weeks of pregnancy after a consultation and transvaginal scan in our preterm birth clinic, and to continue up to 36 weeks of pregnancy.

It is much smaller than a tampon, and dissolves immediately. You may notice that you have a change in vaginal discharge (increased amount and/or more watery). If you are concerned at any point following the use of the pessaries, please contact the maternity triage assessment unit for advice on 0151 290 4489. As it is a natural substance, there are minimal side effects but the most noted include headache, breast tenderness, nausea and cough.

How does it work?

Although the exact mechanism of how progesterone helps to prevent early labour is not confirmed, the evidence seems to favour two ways in which it inhibits uterine contractions:

 An anti-inflammatory effect that counteracts the inflammatory sequences that lead to preterm labour An increase in local progesterone in pregnancy tissues that acts against possible decreased levels which lead to preterm labour

What is the evidence for its use?

Research findings for singleton and multiple pregnancies (twins/triplets) differ slightly, this information resource is specifically for singleton pregnancies.

A growing body of interest has developed into the use of progesterone in the prevention of preterm birth over the past two decades, but the results have not always been clear and has sometimes been conflicting. Most notably is the OPPTIMUM trial, which suggested there was no substantial benefit overall.

However, when pooled together with other high-quality research studies (a metaanalysis), totalling almost 500 patients, vaginal progesterone was shown to have a statistically significant reduction in preterm birth of 34%.

In 2013, a Cochrane review combining 36 trials and 8523 women concluded that progesterone therapy had beneficial effects, including reducing the risk of the baby dying after birth, suffering complications such as requiring breathing support, intestinal disease, prolonging the pregnancy, and reducing the chance of neonatal intensive care admission.

Further multiple large, high-quality research study analyses have reported a reduction in preterm birth, most significantly in women with a short cervical length (where the neck of the womb measures less than 25mm) or a previous preterm birth before 34 and 37 weeks, and a reduction in neonatal death. It has been found to be the only intervention with consistent effectiveness in at-risk pregnancies overall. In 2021, the EPPPIC trial reported that: "Vaginal progesterone reduced birth before 34 weeks' gestation in high-risk singleton pregnancies. Given increased underlying risk, absolute risk reduction is greater for women with a short cervix, hence treatment might be most useful for these women."

Further information

If you would like to discuss further, please do not hesitate to ask any questions with your obstetrician in the preterm birth clinic.

Useful websites:

NIHR Evidence - Updated evidence on progesterone to prevent preterm birth in at-risk pregnancies - Informative and accessible health and care research

Information for the public | Preterm labour and birth | Guidance | NICE



www.sthk.nhs.uk