

# Double blind randomised placebo controlled trial of progesterone for the prevention of preterm birth in twins

<b>Submission date</b> 10/06/2005	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 25/07/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 12/01/2016	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
RN04OB007

## Study information

**Scientific Title**

Double blind randomised placebo controlled trial of progesterone for the prevention of preterm birth in twins

**Acronym**

STOPPIT

**Study objectives**

Vaginal progesterone gel, 90 mg daily from 24-34 weeks gestation, reduces the rate of preterm delivery in twin pregnancy.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Not provided at time of registration

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**Study type(s)**

Prevention

**Health condition(s) or problem(s) studied**

Preterm delivery

**Interventions**

Vaginal progesterone, 90 mg daily for ten weeks from 24 weeks gestation versus placebo

**Intervention Type**

Drug

**Phase**

Not Specified

**Drug/device/biological/vaccine name(s)**

Progesterone

**Primary outcome(s)**

Proportion of women in each group delivering before 34 weeks gestation

**Key secondary outcome(s)**

Pregnancy duration, maternal complication rates, neonatal complication rates, maternal side effects, acceptability of treatment, subject perception of alternatives, perinatal mortality, perinatal morbidity

**Completion date**

30/10/2008

## Eligibility

### Key inclusion criteria

1. Women with twin pregnancy
2. Gestation established by scan before 20 weeks gestation
3. Known chorionicity

### Participant type(s)

Patient

### Healthy volunteers allowed

No

### Age group

Adult

### Sex

Female

### Key exclusion criteria

1. Known significant structural or chromosomal fetal abnormality
2. Contraindications to progesterone
3. Planned cervical suture
4. Planned elective delivery before 34 weeks gestation
5. Intervention for twin to twin transfusion before 22 weeks

### Date of first enrolment

01/11/2005

### Date of final enrolment

30/10/2008

## Locations

### Countries of recruitment

United Kingdom

Scotland

### Study participating centre

University of Glasgow Division of Developmental Medicine

Glasgow

United Kingdom

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# Sponsor information

## Organisation

Greater Glasgow Health Board (North Glasgow University Hospitals Division) and the University of Glasgow (UK)

## ROR

<https://ror.org/05kdz4d87>

# Funder(s)

## Funder type

Government

## Funder Name

Chief Scientist's Office, Scottish Executive (ref no CZH/4/200) (UK)

# Results and Publications

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	13/06/2009		Yes	No
<a href="#">Results article</a>	follow-up results	16/04/2015		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes