ISRCTN35782581 https://doi.org/10.1186/ISRCTN35782581

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

Submission date
10/06/2005

Recruitment status
No longer recruiting

Registration date
25/07/2005

Overall study status
Completed

Last Edited
12/01/2016

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 signficiant 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
G31 2ER

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?
Results article	results	13/06/2009		Yes	No
Results article	follow-up results	16/04/2015		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes