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

Submission date Recruitment status [X] Prospectively registered 10/06/2005 No longer recruiting [] Protocol [] Statistical analysis plan Registration date Overall study status 25/07/2005 Completed [X] Results [] Individual participant data Last Edited Condition category Pregnancy and Childbirth 12/01/2016

Plain English summary of protocol

Not provided at time of registration

Study website

https://medserv.abdn.ac.uk/stoppit/index.php

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

Patient information can be found at: https://medserv.abdn.ac.uk/stoppit/pis.php

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 measure

Proportion of women in each group delivering before 34 weeks gestation

Secondary outcome measures

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

Overall study start date

01/11/2005

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

Age group

Adult

Sex

Female

Target number of participants

500

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

Scotland

United Kingdom

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)

Sponsor details

Research and Development Office
4th Floor, Walton Building
Glasgow Royal Infirmary
84 Castle Street
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United Kingdom
G4 OSF
+44 (0)141 211 0475
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Sponsor type

Hospital/treatment centre

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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 |