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

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

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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
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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