ISRCTN41358726 https://doi.org/10.1186/ISRCTN41358726

Growth Restriction Intervention Trial

Submission date
25/10/2000

Recruitment status
No longer recruiting

Registration date
25/10/2000

Overall study status
Completed

Last Edited
14/07/2014

Condition category
Pregnancy and Childbirth

[ ] 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
G9533539

Study information

Scientific Title

Acronym
GRIT

Study objectives

The aim of this trial is to compare the effect of immediate or delayed delivery for premature fetuses with good evidence of failure to thrive in utero. Cases will be stratified by gestational age and the degree of abnormality of test results. The sole entry criterion will be obstetrician uncertainty about the best management. The primary outcome measure will be Development Quotient at two years of age, with deaths included and scored as zero. The analysis will be stratified by gestation and the degree of test abnormality.

Please note that, as of 14/02/2007, the target number of participants has been updated from 548 to 510 (233 UK; 277 non-UK).

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)
Not Specified

Health condition(s) or problem(s) studied
Obstetrics and gynaecology

Interventions
Immediate delivery or defer delivery until uncertainty no longer exists.

Please note that, as of 14/02/2007, the anticipated start and end dates of this trial have been updated to 01/04/1997 and 27/06/2008, respectively.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Development Quotient at two years of age, with deaths included and scored as zero.

Key secondary outcome(s))
Not provided at time of registration

Completion date
31/01/1996

Eligibility

Key inclusion criteria
1. Gestation between 24 - 36 completed weeks
2. Evidence of pregnancy compromise
3. Clinical uncertainty about the optimum timing of delivery. Entry criteria are flexible since the degree of compromise that would make obstetricians consider delivery vary with gestational age and between clinicians

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
09/01/1994

Date of final enrolment
31/01/1996

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Centre for Reproduction, Growth and Development
Leeds
United Kingdom
LS2 9LN

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	01/01/2003		Yes	No
Results article	results	01/08/2004		Yes	No