Growth Restriction Intervention Trial

Submission date	Recruitment status	Prospectively registered		
25/10/2000	No longer recruiting	☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
25/10/2000	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
14/07/2014	Pregnancy and Childbirth			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr James G Thornton

Contact details

Centre for Reproduction, Growth and Development University of Leeds 34 Hyde Terrace Leeds United Kingdom LS2 9LN

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, 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