




# Growth Restriction Intervention Trial

<b>Submission date</b> 25/10/2000	<b>Recruitment status</b> No longer recruiting	 Retrospectively registered
		 Protocol not yet added
<b>Registration date</b> 25/10/2000	<b>Overall study status</b> Completed	 SAP not yet added
		 Results added
<b>Last Edited</b> 14/07/2014	<b>Condition category</b> Pregnancy and Childbirth	 Raw data not yet added
		 Study completed

## Plain English Summary

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Protocol/serial number

G9533539

## Study information

Scientific Title

**Acronym**

GRIT

**Study hypothesis**

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

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Not specified

**Study type(s)**

Not Specified

**Participant information sheet****Condition**

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 measure**

Development Quotient at two years of age, with deaths included and scored as zero.

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

09/01/1994

**Overall study end date**

31/01/1996

## Eligibility

**Participant 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

**Age group**

Adult

**Sex**

Female

**Target number of participants**

510 (233 UK; 277 non-UK)

**Participant exclusion criteria**

Not provided at time of registration

**Recruitment start date**

09/01/1994

**Recruitment end date**

31/01/1996

## Locations

**Countries of recruitment**

England

United Kingdom

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

## Sponsor information

**Organisation**  
Medical Research Council (MRC) (UK)

**Sponsor details**  
20 Park Crescent  
London  
United Kingdom  
W1B 1AL  
+44 (0)20 7636 5422  
clinical.trial@headoffice.mrc.ac.uk

**Sponsor type**  
Research council

**Website**  
<http://www.mrc.ac.uk>

## Funder(s)

**Funder type**  
Research council

**Funder Name**  
Medical Research Council (UK)

**Alternative Name(s)**  
UK Medical Research Council, MRC

**Funding Body Type**  
Government organisation

**Funding Body Subtype**

National government

## Location

United Kingdom

# 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?
<a href="#">Results article</a>	results	01/01/2003		Yes	No
<a href="#">Results article</a>	results	01/08/2004		Yes	No