

# Leave alone or Induce for the Big BabY

<b>Submission date</b> 21/09/2000	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 21/09/2000	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 27/09/2017	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
G0000515

## Study information

**Scientific Title**  
Leave alone or Induce for the Big BabY: a randomised controlled trial

**Acronym**

LIBBY

**Study objectives**

Does induction of labour for suspected fetal macrosomia confer maternal or fetal benefits?

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Not provided at time of registration.

**Study design**

Pilot study for randomised controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet****Health condition(s) or problem(s) studied**

Suspected fetal macrosomia

**Interventions**

Not provided at time of registration.

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome measure**

1. Fetal birth trauma (Erbs palsy or any fracture, or neonatal convulsions or intra-cerebral haemorrhage or need for admission to intensive care
2. Instrumental vaginal delivery
3. Caesarean section
4. Maternal injury

**Secondary outcome measures**

Not provided at time of registration.

**Overall study start date**

26/07/1999

**Completion date**

18/02/2003

## Eligibility

**Key inclusion criteria**

Not provided at time of registration.

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Female

**Target number of participants**

72 in each group (total = 144)

**Key exclusion criteria**

Not provided at time of registration.

**Date of first enrolment**

26/07/1999

**Date of final enrolment**

18/02/2003

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

Department of Obstetrics and Gynaecology

Nottingham

United Kingdom

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## Sponsor information

**Organisation**

Medical Research Council (MRC) (UK)

**Sponsor details**

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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)**

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****Publication and dissemination plan**

Added 27/09/17: This was a pilot study. The results were given to the Cochrane reviewers and included in the relevant Cochrane Review (see publication summary section). No other publication plans.

**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>	pilot results within Cochrane Review	01/08/2000		Yes	No