

Effect of first trimester crown rump length measurement on rates of induction of labour for postdates.

Submission date 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 03/12/2008	Condition category 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

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

SPGS 757

Study information

Scientific Title

Study objectives

The project is an RCT of the effect of first trimester ultrasound on rates of induction of labour for postdates. Currently it is widespread practice in most obstetric units in the United Kingdom to induce labour 14 days after the estimated date of delivery (EDD). While this has been shown to have a beneficial effect on perinatal outcome, it may cause consumer dissatisfaction as it is perceived to be a painful intervention in an otherwise normal pregnancy. Measurement of the biparietal diameter at 20 weeks gestation has been shown to improve the accuracy of gestational age assessment, and this should lead to a reduction in rates of induction of labour for postdates. Gestational age assessment using CRL in the 1st trimester is more accurate than the biparietal diameter and may further reduce the numbers requiring induction for postdates. There is an increasing shift to perform prenatal diagnosis in the first trimester. Those providing antenatal care may have to choose the best time at which a routine scan in pregnancy can be offered. If a first trimester ultrasound scan is shown to improve the customisation and therefore the appropriateness of obstetric care this would provide further evidence to justify its introduction as well as its use in screening for Down's syndrome, either with nuchal fold or as an adjunct to serum screening.

The objective is to determine whether an ultrasound scan in the first trimester of pregnancy will lead to more accurate assessment of gestational age and consequently lead to a reduction in the number of pregnancies induced at term and fourteen days. If this is the case then there will be cost savings for the NHS, as well as the reduction in unnecessary and potentially painful interventions.

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

Health condition(s) or problem(s) studied

Pregnancy and childbirth: Childbirth

Interventions

The control group will continue with routine antenatal care with ultrasound performed for the usual indications.

The intervention group will have an ultrasound scan between 8 and 12 weeks gestation to measure the crown-rump length (CRL) and if there is a discrepancy of greater than 5 days between the estimated date of delivery (EDD) calculated from the last menstrual period and that by CRL the EDD will be revised to that derived by scan. The EDD will be entered in the patient's obstetric notes and all subsequent management decisions will be based on this assessment of gestational age.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Rates of induction of labour for postdates

Secondary outcome measures

1. The characteristics of labour with respect to the length of labour, the mode of delivery, the immediate perinatal outcome, analgesic requirements for labour and the overall client satisfaction with labour
2. Rates of gestation dependent events in pregnancy - false positive and negative outcomes from maternal serum screening
3. The management of early pregnancy complications

Overall study start date

01/02/1999

Completion date

30/09/2002

Eligibility**Key inclusion criteria**

Women in the first trimester of pregnancy who do not require a first trimester ultrasound for any other clinical indication.

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

Added December 2008: 800 intended

Key exclusion criteria

Women will be excluded if there is a clinical indication for a first trimester ultrasound scan or if they refuse consent. Examples of the former would be if there was vaginal bleeding, uncertainty about viability of the pregnancy or the possibility of an ectopic pregnancy.

Date of first enrolment

01/02/1999

Date of final enrolment

30/09/2002

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Nuffield Department of Obstetrics and Gynaecology

Oxford

United Kingdom

OX3 9DU

Sponsor information**Organisation**

NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details

The Department of Health

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Sponsor type

Government

Website

http://www.doh.gov.uk

Funder(s)

Funder type

Government

Funder Name

NHS Executive South East (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 of uncompleted trial	01/02/2006		Yes	No