

Home Blood Pressure Recording in Pregnancy - A Pilot Study for a Randomised Trial

Submission date 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 21/01/2010	Condition category Pregnancy and Childbirth	<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
HSR/037

Study information

Scientific Title

Study objectives

The traditional model of antenatal care often involves 14 or more clinical visits but there is large practice variation. The detection of hypertension is an important function of antenatal care and, unless blood pressure can be monitored outside the clinic, this sets a lower limit on the frequency of visits. We propose a pilot study (prior to embarking on a larger trial) where women would be randomised to receive EITHER routine antenatal visits and clinic monitoring of blood pressure OR a reduced number of antenatal visits and home monitoring of blood pressure. The pilot will investigate what proportion and types of women are willing to take part in such a study and whether women use portable blood pressure monitors satisfactorily and at the prescribed times. It will also be sufficient to measure major effects on anxiety and number of attendances.

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)

Other

Study type(s)

Screening

Participant information sheet

Health condition(s) or problem(s) studied

Pregnancy and hypertension

Interventions

1. Routine antenatal visits and clinic monitoring of blood pressure
2. A reduced number of antenatal visits and home monitoring of blood pressure.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Recruitment
2. Total number of clinic visits
3. Frequency of blood pressure measurements
4. Schedule preference
5. Anxiety

Secondary outcome measures

Not provided at time of registration

Overall study start date

25/03/1996

Completion date

24/09/1997

Eligibility

Key inclusion criteria

Pregnant women

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

80 (added 21/01/10; see publication)

Key exclusion criteria

1. Multiple pregnancies
2. Established hypertension
3. Previous early-onset pre-eclampsia
4. Serious medical disease
5. Previous pregnancy loss after 24 weeks

Date of first enrolment

25/03/1996

Date of final enrolment

24/09/1997

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Academic Unit of Psychiatry and Behavioural Sciences

Leeds

United Kingdom

LS2 9LT

Sponsor information

Organisation

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

Sponsor details

The Department of Health

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London

United Kingdom

SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Government

Funder Name

NHS Executive Northern and Yorkshire (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	01/02/2000		Yes	No