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

Submission date	Recruitment status	[_] Prospectively registered
23/01/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/01/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
21/01/2010	Pregnancy and Childbirth	

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
Richmond House
79 Whitehall
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