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Antenatal screening for haemoglobinopathies in primary care: a cluster randomised trial to inform a simulation model

Submission date	Recruitment status	[X] Prospectively registered
30/04/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/04/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
31/01/2012	Haematological Disorders	

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

HTA 03/02/03

Study information

Scientific Title

Acronym
SHIFT (Screening for Haemoglobinopathies In the First Trimester)

Study objectives
Offering antenatal screening for sickle cell and thalassaemia when women first report their pregnancy as opposed to offering it as part of community based secondary care increases the proportion of women who know their carrier status before ten weeks gestation.

Protocol can be found at: http://www.ncchta.org/protocols/200300020003.pdf
More information can be found at: http://www.hta.ac.uk/1401

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee on the 23rd March 2005 (ref: 05/Q0501/36)

Study design
Partial factorial cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Sickle cell and thalassaemia

Interventions

Please note that the anticipated end date of this trial has been extended to 30 April 2008 as of 14 December 2007 (Anticipated end date provided at time of registration: 30 September 2007). Closed to recruitment of participants: follow-up continuing.

A partial factorial cluster randomised controlled trial with general practice as the unit of randomisation. Participating general practices will be randomised to offering screening in one of three ways:
Group 1: In primary care, when women first report their pregnancies with parallel partner testing (i.e. partners of all women are offered screening at the same time as the pregnant women)
Group 2: In primary care, when women first report their pregnancies with sequential partner testing; (i.e. partners of women are only offered screening if the pregnant woman is found to be a carrier)
Group 3: In community-based secondary care, when women are booked by midwives with sequential partner testing

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Time in pregnancy of offer of carrier screening for sickle cell and thalassaemia
2. Time in pregnancy of testing for carrier status for sickle cell and thalassaemia

Secondary outcome measures
1. Rates of informed choice about undergoing the screening test
2. Time in pregnancy when women know the carrier status of the babys father
3. Couples emotional responses to carrier testing after they have received their test result

Overall study start date
01/10/2004

Completion date
30/04/2008

Eligibility

Key inclusion criteria
1. Eligible pregnant women receiving antenatal care at participating general practices
2. Aged 18 and over
3. Wanting to continue with the pregnancy
4. Carrier status is not documented in primary care records

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
990 women and 330 partners

Key exclusion criteria
1. Women who do not want to continue with the pregnancies
2. Women who are more than 18 weeks gestation when reporting their pregnancies

Date of first enrolment
01/10/2004

Date of final enrolment
30/04/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
King's College London
London
United Kingdom
SE1 9RT

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Quarry House
Quarry Hill
Leeds
United Kingdom
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Sponsor type
Government

Website
http://www.dh.gov.uk/en/index.htm

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (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 published by funding body	01/04/2010		Yes	No
Results article	results published by the BMJ	05/10/2010		Yes	No
Results article	results published by Journal of Medical Screening	01/10/2011		Yes	No