

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

Submission date 30/04/2004	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 30/04/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 31/01/2012	Condition category Haematological Disorders	<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

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.nchta.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 baby's 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

LS2 7UE

Sheila.Greener@doh.gsi.gov.uk

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