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Prenatal and neonatal screening of haemoglobinopathies: a prospective study

Submission date	Recruitment status	[ ] Prospectively registered
28/04/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/04/2006	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
02/09/2008	Haematological Disorders	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr J.L.H. Kerkhoffs

Contact details
HagaHospital
Leyweg 275
The Hague
Netherlands
2545 CH
+31 (0)70 3592004
J.Kerkhoffs@hagaziekenhuis.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
METC-nr 05-83; NTR622

Study information

Scientific Title

Study objectives
The carrier frequence of haemoglobinopathies is greater than 0.05 and screening for primary prevention is cost-effective.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Cross sectional study

Primary study design
Observational

Secondary study design
Cross-section survey

Study setting(s)
Not specified

Study type(s)
Screening

Participant information sheet

Health condition(s) or problem(s) studied
Haemoglobinopathies

Interventions
Unselected group of pregnant females (n = 1000) and a group of newborns (n = 1000) will be screened for haemoglobinopathies.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Carrier frequence of haemoglobinopathies.

Secondary outcome measures

1. Serum ferritin
2. Compliance to prenatal testing
3. Cost-effectiveness

Overall study start date
01/03/2006

Completion date
28/02/2007

Eligibility

Key inclusion criteria
1. Pregnant females before the 16th week of pregnancy and newborns
2. Informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
2000

Key exclusion criteria
Known haemoglobinopathy

Date of first enrolment
01/03/2006

Date of final enrolment
28/02/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
HagaHospital
The Hague
Netherlands
2545 CH

Sponsor information

Organisation
HagaZiekenhuis (The Netherlands)

Sponsor details
Leyweg 275
The Hague
Netherlands
2545 CH

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03q4p1y48

Funder(s)

Funder type
Research organisation

Funder Name
The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

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