

Pre- and neonatal screening of hemoglobinopathies: a prospective study.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26283

Source

NTR

Brief title

Screening of hemoglobinopathies

Health condition

Hemoglobinopathies

Sponsors and support

Primary sponsor: No

Source(s) of monetary or material Support: Request for funding is submitted (ZonMw)

Intervention

Outcome measures

Primary outcome

Carrier frequency of hemoglobinopathies.

Secondary outcome

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

Study description

Background summary

In a period of 2 years an unselected group of pregnant females ($n = 1000$) and a group of newborns ($n = 1000$) will be screened for hemoglobinopathies.

Primary endpoint is the carrier frequency of hemoglobinopathies, secondary endpoints are the compliance to prenatal testing, iron stores and cost-effectiveness.

Study objective

The carrier frequency of hemoglobinopathies is $> 0,05$ and screening for primary prevention is cost-effective.

Study design

N/A

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

Known hemoglobinopathy.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2006
Enrollment:	2000
Type:	Actual

Ethics review

Positive opinion

Date: 31-01-2006

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL566
NTR-old	NTR622
Other	MEC : 05-83
ISRCTN	ISRCTN88941850

Study results

Summary results

P.C. Giordano et al. A confidential inquiry estimating the number of patients affected with sickle cell disease and thalassemia major confirms the need for a preventive strategy in the Netherlands. *hemoglobin* (2004),28: 287-296

Disorders of hemoglobin. Genetics, pathophysiology and clinical management. Edit by Steinberg et al. Cambridge Univ. Press 2001