

Risk perception, informed decision making, and psychological well-being of pregnant women who are offered prenatal screening for congenital defects

Submission date 27/01/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 27/01/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 03/07/2009	Condition category Neonatal Diseases	<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

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Study objectives

Not provided at time of registration

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Study design

Randomised, single blind, controlled, parallel group 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

Down syndrome, neural tube defect

Interventions

The offer of a prenatal screening test (either the nuchal translucency measurement, or the maternal serum screening test) by means of an information booklet and an oral explanation by the woman's midwife or gynaecologist

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Risk perception
2. Psychological well-being

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/2000

Completion date

31/12/2005

Eligibility

Key inclusion criteria

Pregnant women attending 1 of 44 participating midwifery or gynaecology practices from May 2001 to May 2003 were asked for their informed consent.

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

3000

Key exclusion criteria

1. Gestational age of more than 16 weeks
2. No command of the Dutch language

Date of first enrolment

01/01/2000

Date of final enrolment

31/12/2005

Locations

Countries of recruitment

Netherlands

Study participating centre

VU University Medical Centre

Amsterdam

Netherlands

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Sponsor information

Organisation

VU University Medical Center, EMGO-Institute and Department of Public and Occupational Health (Netherlands)

Sponsor details

Van der Boechorststraat 7
Amsterdam
Netherlands
1081 BT
emgo@vumc.nl

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/00q6h8f30>

Funder(s)

Funder type

Research organisation

Funder Name

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

Study outputs

Output	Date	Date	Peer	Patient-
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type	Details	created	added	reviewed?	facing?
Results article	results on test uptake and participants' reasons	01/01/2005		Yes	No
Results article	results on informed decision making about prenatal screening among participants	01/05/2005		Yes	No