

Parental Attitude towards CL \pm P during pregnancy;To evaluate and obtain insight into psychological, social and moral factors in order to improve counseling.

Published: 24-05-2011

Last updated: 06-05-2024

To evaluate and obtain insight into psychological, social and moral factors in thoughts and attitudes of pregnant women and their partners carrying a fetus with an isolated CL \pm P in order to improve counseling.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Skin and subcutaneous tissue disorders congenital
Study type	Observational non invasive

Summary

ID

NL-OMON36781

Source

ToetsingOnline

Brief title

Parental Attitude towards CL \pm P during pregnancy

Condition

- Skin and subcutaneous tissue disorders congenital
- Abortions and stillbirth

Synonym

orofacial cleft

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: burden, orofacial cleft, termination

Outcome measures

Primary outcome

Psychological, social and moral factors in thoughts and attitudes of pregnant women and their partners carrying a fetus with an isolated CL \pm P .

Secondary outcome

- To describe parental interpretation of CL \pm P (is it a threat, disability, disease or a handicap) of CL, and whether they interpret this condition as severe or not severe.
- To describe the influences from external contact (partner/family and friends/professionals) on parental thoughts and attitude.

Study description

Background summary

Ultrasound (US) screening for cleft lip (CL) and cleft palate (CP) at 20-weeks of pregnancy was introduced by practice in 2007, and at present more than 90% of Dutch pregnant women use this opportunity. The counseling process of future parents who are confronted with a prenatal diagnosis of orofacial cleft is in it*s infancy. It would be valuable to analyse if there is a need for improvement. The counseling process is never analysed before.

Study objective

To evaluate and obtain insight into psychological, social and moral factors in thoughts and attitudes of pregnant women and their partners carrying a fetus with an isolated CL \pm P in order to improve counseling.

Study design

A Cross Sectional Quantitative Survey will be performed, with questionnaires.

Study burden and risks

There are no specific risks or benefits for the participants, although the matter of the questions can be emotionally aggravating. For the latter parents can ask counseling of a medical psychologist. The filling out of the questionnaires will take approximately 30 minutes of their time and can be done at home. The participants will remain anonymously.

Contacts

Public

Universitair Medisch Centrum Utrecht

Heidelberglaan 100
3584 CX Utrecht
NL

Scientific

Universitair Medisch Centrum Utrecht

Heidelberglaan 100
3584 CX Utrecht
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

3 - Parental Attitude towards CL \pm P during pregnancy;To evaluate and obtain insight ... 24-05-2025

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Pregnant women and their partners
2. Age: ≥ 18 years
3. Referred to Department of Obstetrics and Gynaecology Wilhelmina Children's Hospital, Utrecht
4. Isolated CL \pm P is detected on US
5. Before 24 weeks* gestation

Exclusion criteria

1. Associated anomalies detected on ultrasound.
2. Median cleft
3. Pregnant women and their with a psychiatric disease or other conditions making them incapable of filling out the questionnaire.
4. Pregnant women and their partners incapable of filling out the questionnaire because of a language barrier.
5. Participants who do not filling out the required percentage for relevant inventory, which is 99%.

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-08-2011

Enrollment: 100

Type: Actual

Ethics review

Approved WMO

Date: 24-05-2011

Application type: First submission

Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

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
CCMO	NL27986.041.09