# Field testing the CLEFT-Q

No registrations found.

**Ethical review** Not applicable

**Status** Pending

Health condition type -

**Study type** Observational non invasive

### **Summary**

#### ID

NL-OMON24585

Source

NTR

#### **Health condition**

Quality of Life Patient Reported Outcome Measure Cleft patients

### **Sponsors and support**

**Primary sponsor:** University Medical Centre Groningen

Source(s) of monetary or material Support: McMasters University, Canada

#### Intervention

#### **Outcome measures**

#### **Primary outcome**

Outcome of the study: An internationally validated PROM for use by patients with cleft lip and/or palate.

#### **Secondary outcome**

not applicable

## **Study description**

#### **Background summary**

So far outcomes in cleft treatment have mainly been measured in objective and biomedical outcomes. Patient perspectives are often overlooked, because an appropriate, well-defined, valid, reliable and responsive Patient Reported Outcome measurement tool is not available. An international team of experts from Candada, USA and UK has taken up the challenge and is developing this PRO instrument, called the CLEFT-Q. The cleft team in the UMCG/MCL will take part in field testing the CLEFT-Q

#### Study design

not applicable

#### Intervention

Subjects will fill in a Patient reported outcome measure

### **Contacts**

#### **Public**

Hanzeplein 1 M. Dreise Groningen 9700 RB The Netherlands +31 (0)50 3610269

#### Scientific

Hanzeplein 1 M. Dreise Groningen 9700 RB The Netherlands +31 (0)50 3610269

## **Eligibility criteria**

### **Inclusion criteria**

- \* Children/adolescents with CL, CP, CLP between 6 and 29 years of age.
- \* Who gave written informed consent (and/or their parents in case of minors)

- \* who are under treatment in our centres or
- \* who had treatment in our centres in the past:

#### **Exclusion criteria**

- \* Children with a cognitive disability and/or who cannot read.
- \* Children who do not understand/speak Dutch.

## Study design

### **Design**

Study type: Observational non invasive

Intervention model: Other

Masking: Open (masking not used)

Control: N/A, unknown

#### Recruitment

NI

Recruitment status: Pending

Start date (anticipated): 16-01-2015

Enrollment: 200

Type: Anticipated

### **Ethics review**

Not applicable

Application type: Not applicable

## **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	NL4794
NTR-old	NTR4934
CCMO	NL 51730

# **Study results**