

Analysis of patient reported outcome after correction of sagittal synostosis

Gepubliceerd: 17-07-2014 Laatste bijgewerkt: 18-08-2022

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON25313

Bron

NTR

Aandoening

Sagittal synostosis, patient related outcome measure, surgery

Ondersteuning

Primaire sponsor: Erasmus University Medical Center

Overige ondersteuning: no funding

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

response to questionnaire, represented and analysed on ordinal scale. Correlation with cranial index and photographic outcome score.

Toelichting onderzoek

Achtergrond van het onderzoek

Analysis of Patient Reported Outcome Measure after correction for sagittal suture synostosis and validation with other outcome parameters.

Early closure of the sagittal suture results in restricted growth of the skull width and compensatory growth of the skull length. The resulting head shape is called scaphocephaly. Surgical remodeling of the skull is performed within the first year of life for functional and cosmetic reasons (1).

Cosmetic results are difficult to score in an objective fashion.

An important method to assess cosmetic results is to ask the patient about their satisfaction with the cosmetic results in a standardized questionnaire called Patient-Reported Outcome Measure (PROM)(2).

The goal of this study is to develop an outcome parameter that adequately reflects the patient's appreciation of the cosmetic result of remodeling. The questionnaire consists of 10 questions to be answered on a 5 point scale. The PROM will be validated with other outcome parameters like Cranial Index and photographic scores.

The PROM will be sent to patients between 6 and 18 years old who underwent surgery in their first year of life in the Dutch Craniofacial Center for sagittal suture synostosis.

References

1. Wong KW, Forrest CR, Goodacre TE, Klassen AF. Measuring outcomes in craniofacial and pediatric plastic surgery. Clinics in plastic surgery. 2013 Apr;40(2):305-

12.

2. Pusic AL, Lemaine V, Klassen AF, Scott AM, Cano SJ. Patient-reported outcome measures in plastic surgery: use and interpretation in evidence-based medicine. Plastic and reconstructive surgery. 2011 Mar;127(3):1361-7.

Onderzoeksopzet

One observation between the age of 6 and 18 years

Onderzoeksproduct en/of interventie

1 questionnaire

Contactpersonen

Publiek

Neurosurgeon

Dutch Craniofacial Center

Erasmus University Medical Center Rotterdam
M.L.C. Veelen, van
Rotterdam
The Netherlands

Wetenschappelijk

Neurosurgeon

Dutch Craniofacial Center

Erasmus University Medical Center Rotterdam
M.L.C. Veelen, van
Rotterdam
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

patients who underwent correction for sagittal synostosis at the dutch craniofacial study and are momentarily between 6 and 18 years old.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients that do not meet the age criteria to fill in the questionnaire.

Patients with complex synostosis.

Onderzoeksopzet

Opzet

Type: Observationeel onderzoek, zonder invasieve metingen

Onderzoeksmodel: Anders

Controle: N.v.t. / onbekend

Deelname

Nederland

Status: Werving nog niet gestart

(Verwachte) startdatum: 01-10-2014

Aantal proefpersonen: 120

Type: Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort: Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4554
NTR-old	NTR4697
Ander register	: MEC-2014-445

Resultaten