Black bone MRI in unisutural craniosynostosis patients.

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Primary Objective: To validate the predictive value of MRI data for neurocognitive deficits and visual functioning by relating these data from newborns with unisutural craniosynostosis to the psychological and ophthalmologic test results, taken…

Ethical review	Approved WMO
Status	Pending
Health condition type	Congenital and hereditary disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON46249

Source
ToetsingOnline

Brief title
BBMRI Cranio

Condition

- Congenital and hereditary disorders NEC

Synonym
a medical condition in which some or all of the sutures in the skull of an infant close too early

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: ASL, Craniosynostosis, DTI, MRI

Outcome measures

Primary outcome

Main parameters are the DTI and ASL data and ophthalmologic data from the black bone MRI, and the psychological test data taken at 2, 4, and 6 years of age.

The inclusion of patients for black bone MRI stops after 2 years if a sufficient number of patients is included, while the study stops once the last included patient has had its final psychological assessment at 6 years of age.

Secondary outcome

na

Study description

Background summary

In unisutural craniosynostosis, a single suture of the skull vault is closed before birth, and normal growth of the skull and brain is restricted. This particularly involves the sagittal suture, the metopic suture and the coronal suture. Besides an abnormal skull shape, additional related problems are encountered. Children with sagittal synostosis are reported to have a higher prevalence of speech/language impairment, while metopic synostosis puts children at risk for disturbed behaviour, particularly attention deficiency hyperactivity disorder (ADHD) and autism, and amblyopia (Nguyen 2014). Coronal synostosis is specifically related to visual disturbances, such as strabismus and amblyopia. These associated problems can only be detected at an older age, when screening of speech/language, behaviour, and vision can be performed reliably. Screening is routinely done at the ages of 2, 4 and 6 years of age as part of the clinical protocol. It is unknown why these children have a synostosis-specific higher risk on associated problems, and whether or not this can be predicted early on. Early detection of neurocognitive and visual deficiencies would enable early management and improved counselling of the parents.

Specifically for metopic synostosis there is a debate on whether or not to perform surgery for the moderate phenotype (Anolik et al., 2016; Birgfeld et al., 2013). The earlier the fusion of the suture occurs during embryogenesis, the more severe the phenotype is. Treatment of the severe presentation of trigonocephaly consist of surgical correction of the frontal bones and supra-orbital rims, for which there is consensus on surgical indication. There is however no consensus whether or not to perform surgery for the intermediate form, because the benefits regarding neurocognitive functions are unknown.

Study objective

Primary Objective:
To validate the predictive value of MRI data for neurocognitive deficits and visual functioning by relating these data from newborns with unisutural craniosynostosis to the psychological and ophthalmologic test results, taken routinely at the ages of 2, 4 and 6 years.

Secondary Objective: To test ASL as an objective criterium for a surgical indication by comparing cerebral blood flow in trigonocephaly with norm data and by relating it to the severity of the phenotype.

Study design

An observational pilot study of a cohort with longitudinal follow-up. The study will take around 2 years of inclusion for BB MRI. The number of referred patients per year is 40 for sagittal synostosis, 15 for metopic synostosis, and 5 for unicoronal synostosis, and will thus have a total of 100 potential patients for inclusion. The final results of the study will take 7 years to have the final psychological test at age 6 included. No extra visits to the hospital will be required for the participants, as we can combine the MRI procedure with other routinely scheduled visits. Within out center, we have age-specific control data for both DTI and ASL.

Study burden and risks

The benefit of participation is the avoidance of radiation that is associated with a 3D-CT scan of the head. Another potential advantage could be the early detection of intrinsic brain disorders that are associated with neurocognitive impairments, enabling earlier treatment by psychologists and ophthalmologist. The risk lies in having anesthesia for a period of 45 minutes. The associated risks for anesthesia are very low, based on our own experience within the Sophia Children*s Hospital; in patients with syndromic craniosynostosis a brain MRI is taking with the use of anesthesia according to protocol, as a high prevalence of brain anomalies are present in this group, and no complications have been encountered.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

- informed consent from the parents
- no syndromic diagnosis (i.e. additional congenital anomalies besides the craniosynostosis)
- aged between 3 and 12 months
- regarding trigonocephaly: moderate and severe presentation for which surgery is considered

Exclusion criteria

- no informed consent from the parents
- syndromic diagnosis
- older than 12 months of age
- mild trigonocephaly

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2018
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO Date:	21-09-2018
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL66042.078.18