The non-operative correction of congenital ear anomalies

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Ethical review	Approved WMO
Status	Completed
Health condition type	Ear and labyrinthine disorders congenital
Study type	Interventional

Summary

ID

NL-OMON50799

Source
ToetsingOnline

Brief title
NOCEA

Condition

- Ear and labyrinthine disorders congenital

Synonym
conchal crus, Prominent ears

Research involving
Human

Sponsors and support

Primary sponsor: Zuyderland Medisch Centrum
Source(s) of monetary or material Support: externe subsidie.

Intervention

Keyword: Anomaly, Congenital, Correction, Ear

Outcome measures

Primary outcome

Correction grade of ear anomaly

Secondary outcome

Number and kind of complications

Recurrence rate

Technique satisfaction

Age at initiation

Duration of treatment

Treatment costs

Compliance

Breast feeding

Kind of ear anomaly

Ethnicity

Gender

Family history

Study description

Background summary

5% of Dutch babies is born with a congenital ear anomaly. These anomalies may lead to bullying at a young age, causing psychosocial consequences to affect the child. Due to this reason, children often want an early treatment, which is only possible through operative correction at the minimal age of 5-7. Such a

surgery, also known as an otoplasty, will not always solve the psychosocial consequences, while children may experience additional ones due to the surgery. Possible surgical complications, such as hematoma, excessive scarring or skin necrosis, may lead to additional operative interventions.
Since the twentieth centrury, a new treatment method has arisen; ear molding. Ear molding uses external pressure to reshape the ear to its normal shape. Treatment is initiated at a neonatal age, which leads to evasion of surgical complications and bullying, including their psychosocial consequences. Since 2010, a system has been developed able to treat almost all different kinds of ear anomalies through a standardized use, the EarWell Infant Corrective System. Research has shown that more than 90% of treated ears shows favorable, satisfactory results. Despite being researched in multiple countries, EarWell and ear molding remain relatively new techniques in need of further investigation before it can root in Healthcare.

Study objective

Through this research, we want to further investigate the concept of ear molding through the use of the EarWell Infant Corrective System, this time in the Dutch population. We hope to investigate the opinion on the treatment within the Dutch population and evaluate the results of its use. Eventually, we hope to collect enough evidence for the effectivity and satisfaction in an attempt to let ear molding be included in insured healthcare.

Study design

Neonates will be included and be treated for their ear anomaly with the EarWell system. They will come to follow-up visits every 2 weeks to evaluate correction grade and complications. Treatment will last a minimal of 6 weeks. If there is no correction after 6 weeks or if complications arise which cannot be solved through moving the system, treatment will be terminated. Collected data will be used. With every visit, a questionnaire will be filled out.

Intervention

Treatment will take place in the following manner:
1. Patients will come to the outpatient clinic with their parents for treatment information and consent.
2. The treatment system will be applied if parents agree with the treatment.
3. Every two weeks, patients will return to the outpatient clinic to evaluate the treatment effect.
4. If after 6 weeks, no effect is objectified by both parents and physician, the treatment will be terminated.
5. If complications such as pressure ulcers are seen during the treatment period, the system will be reapplied to relieve pressure on the site of the pressure ulcer.

6. If complications arise that are untreatable through temporary relief of the system or topical treatment, the treatment will be terminated.
7. Treatment will be continued for two weeks after stabilisation of correction
8. In case parents do not give their consent to start treatment, they will be asked to return at 6 months of age and at 12 months of age to evaluate the self-correction of the ear anomaly.
9. In case treatment needs to be terminated due to complications or ineffectiveness, participants will be asked to return at 6 months of age and at 12 months of age to evaluate the self-correction of the ear anomaly.

Study burden and risks

There have been several reports of potential complications. There have been reports of skin excoriations or pressure ulcers and skin irritation/rash. All of the complications were minor in kind and most spontaneously resolved. Another potential *risk* described in the studies is the recurrence of the ear anomaly. This often involved the prominent ears, which have been known to develop during the first year of life, possibly due to posterior pressure from lying supine.
Benefits of the treatment outweighed the risks involved. Due to the high satisfactory correction rate, most children no longer needed operative treatment later in life, which would have exposed the children to more severe possible complications, such as skin necrosis and hematoma. Correction also led to not being exposed to bullying, which annihilated the psychosocial consequences children experienced from this ear-related bullying.

Contacts

Public
Zuyderland Medisch Centrum

Dr. H van Hoffplein 1
Sittard-Geleen 6162 BG
NL
Scientific
Zuyderland Medisch Centrum

Dr. H van Hoffplein 1
Sittard-Geleen 6162 BG
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Congenital ear anomaly (deformations and malformations such as constricted ear or cryptotia)
<12 weeks of age

Exclusion criteria

Syndromal anomalies
Certain malformations (microtia and anotia)
Other pathology in need of more urgent conditions
>12 weeks of age

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed

Start date (anticipated):	26-04-2021
Enrollment:	75
Type:	Actual

Medical products/devices used

Generic name:	EarWell Infant Corrective System
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	04-03-2021
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL75902.096.20