

EPOS RESEARCH GRANT APPLICATION 2021

The correlation between clinical outcomes and quality-of life with clubfoot treatment and treatment of clubfoot recurrence in school age children. A multi-centre study.

Background

The Ponseti method of clubfoot treatment has become the gold-standard of primary care for congenital clubfoot around the world (1,2). However, the rate of recurrence, treatment of recurrence and the frequency of open release surgery show wide variation and increases with the duration of follow up (3-7). It has been shown that patients treated by joint sparing surgery had higher scores in quality-of life studies compared to patients treated with open joint surgery (8), more so, looking at longer term follow-up (9). However, most quality-of-life studies look at defined treatment groups and/or report quality of life in patient samples that are too small to identify related outcome parameters of treatment modifiers (10,11).

Aim

The aim is to undertake an international multicentre study investigating clinical and health-related quality of life outcomes in school age children with Idiopathic CTEV who were treated according to the Ponseti method.

Hypotheses

The primary and secondary hypothesis as follows:

1. Children who did not experience relapse of the deformity have a better clinical and Quality of life outcomes at age 6-10 and 10-14 than children who experienced relapse.
2. There is a negative correlation between children undergoing surgical intervention for clubfoot recurrence and outcomes at age 6-10 and 10-14 with the effect depending on the extent of surgical intervention.

Methods

This study will be undertaken in multiple international centres. A Co-Chief investigator from St Georges University Hospital, London and Orthopaedic Hospital Vienna, Speising. Both CVs are included in this application.

Appropriate approval from local research ethics boards will be sought in advance of the study commencement and will be one of the conditions of participating in the study. A minimum of 40 participants will be required to allow participation.

As this is an observational study there will be no change in the standard local treatment for the patients recruited. The decision for surgical intervention would be at the discretion of the treating clinician.

Population

Inclusion criteria

Idiopathic clubfoot treated in the participating centre according to the Ponseti method

Age: two age groups; one between 6 and 10 years old and the second between 10 and 14.

Exclusion criteria

Non idiopathic clubfoot (i.e arthrogyrosis, spina bifida, neurological involvement)

Previous intervention at another centre prior to referral

Intervention

All patients achieved primary correction according to the Ponseti method including p/c tenotomy.

The patients who experienced recurrence who underwent one or several surgical interventions (tendon lengthening, tendon transfer, soft tissue release [i.e PMR,PLR,PR], bony surgery, circular frame distraction, hemiepiphysiodesis)

Comparator

As this is an observational trial, there is no comparator intervention.

Outcome measures

Primary outcome measure

- Core Outcome Set (12), table attached.

Secondary outcome measures

- The Pediatric Outcomes Data Collection Instrument (PODCI) score for quality-of-life assessment (13)
- Surgical complications

The data collected will include demographics, treatment data including number of casts and type and dates of surgical interventions as well as complications.

Statistical analysis will include a multivariate analysis and regression model to detect treatment and outcome variables associated with decreased scores in the COS and PODCI.

Participation of 10-15 centres is expected with an average of 50 patients per centre and 500-750 cases included.

Costings for the study

Please find below the proposed costings for the study.

1. Research nurses at both sites at 15% FTE (full time equivalent) for 12 months equates to £8700 or 10000 Euros in total. This research nurse will work with Co-Chief Investigators and Principal Investigators (PI) from each site. They will liaise with patients, schedule appointment for COS collection and administer questionnaires.
2. The Co-Chief Investigators will not incur any cost as this work will be undertaken as part of their supporting professional activities time in their job plan.
3. The COS collection will be undertaken by an independent clinician during a clinic appointment. This clinician will not incur any cost as this work will be undertaken as part of their clinical activity.

Literature:

1. Zionts LE, Sangiorgio SN, Ebramzadeh E, Morcuende JA. The current management of idiopathic clubfoot revisited: results of a survey of the POSNA membership. *J Pediatr Orthop*. 2012;32(5):515-20.
2. Shabtai L, Specht SC, Herzenberg JE. Worldwide spread of the Ponseti method for clubfoot. *World J Orthop*. 2014;5(5):585-90.
3. Sangiorgio SN, Ebramzadeh E, Morgan RD, Zionts LE. The Timing and Relevance of Relapsed Deformity in Patients With Idiopathic Clubfoot. *J Am Acad Orthop Surg*. 2017;25(7):536-545.
4. Siebert MJ, Karacz CM, Richards BS. Successful Ponseti-treated Clubfeet at Age 2 Years: What Is the Rate of Surgical Intervention After This? *J Pediatr Orthop*. 2020;40(10):597-603.
5. Hosseinzadeh P, Kiebzak GM, Dolan L, Zionts LE, Morcuende J. Management of Clubfoot Relapses With the Ponseti Method: Results of a Survey of the POSNA Members. *J Pediatr Orthop*. 2019;39(1):38-41.
6. Gelfer Y, Hughes KP, Fontalis A, Wientroub S, Eastwood DM. A systematic review of reported outcomes following Ponseti correction of idiopathic club foot. *Bone Jt Open*. 2020;1(8):457-464.. doi:10.1302/2633-1462.18.BJO-2020-0109.R1
7. Gelfer Y, Wientroub S, Hughes K., Fontalis A, Eastwood DM. Congenital talipes equinovarus A systematic review of relapse as a primary outcome of the Ponseti method. *Bone Joint J 2019;101B*(6), 639-645. doi:[10.1302/0301-620X.101B6.BJJ-2018-1421.R1](https://doi.org/10.1302/0301-620X.101B6.BJJ-2018-1421.R1)
8. Dietz FR, Tyler MC, Leary KS, Damiano PC. Evaluation of a disease-specific instrument for idiopathic clubfoot outcome. *Clin Orthop Relat Res*. 2009;467(5):1256-62.
9. Smith PA, Kuo KN, Graf AN, Krzak J, Flanagan A, Hassani S, Caudill AK, Dietz FR, Morcuende J, Harris GF. Long-term results of comprehensive clubfoot release versus the Ponseti method: which is better? *Clin Orthop Relat Res*. 2014;472(4):1281-90.
10. Khan AA, Abarca N, Cung NQ, Lerman JA. Use of PROMIS in Assessment of Children With Ponseti-treated Idiopathic Clubfoot: Better Scores With Greater Than 3 Years of Brace Use. *J Pediatr Orthop*. 2020;40(9):526-530.
11. Masrouha KZ, Moses MJ, Sala DA, Litrenta J, Lehman WB, Chu A. The Validity of Patient-reported Outcome Measurement Information System (PROMIS) Parent Proxy Instruments to Assess Function in Children With Talipes Equinovarus. *J Pediatr Orthop*. 2019;39(10):e787-e790.
12. Leo DG, Russell A, Bridgens A, Perry DC, Eastwood DM, Gelfer Y. Development of a core outcome set for idiopathic clubfoot management. *Bone Jt Open*. 2021;2(4):255-260. doi:10.1302/2633-1462.24.BJO-2020-0202.R1
13. Haynes RJ, Sullivan E. The Pediatric Orthopaedic Society of North America pediatric orthopaedic functional health questionnaire: an analysis of normals. *J Pediatr Orthop*. 2001;21:619-621.

Table: COS document

Definition
The corrected foot : <ul style="list-style-type: none">• is one in which the talar head is covered, the heel is in neutral or valgus, the anterior process of the os calcis has rotated out from under the talus and where the ankle has 15 degrees of dorsiflexion.• is one that fits comfortably into the boots and bar.
Timing
<ul style="list-style-type: none">• The minimum follow-up for meaningful COS reporting is five years.
Outcome Measures
<ul style="list-style-type: none">• To be assessed yes/no
1. General
<ul style="list-style-type: none">• Recurrence: any change in clinical presentation of the fully corrected foot (following initial management) that requires further treatment.
2. Clinical outcome
Static: <ul style="list-style-type: none">• Is there any fixed deformity?
Dynamic: <ul style="list-style-type: none">• Can the child:<ul style="list-style-type: none">○ Walk○ Run○ Hop• Is there any in-toeing originating from the foot?
PBS score <ul style="list-style-type: none">• Hindfoot varus in standing• Supination in standing• Swing phase supination in walking• Early heel rise in stance when tibia perpendicular in walking• Passive ankle dorsiflexion in sitting• Active ankle dorsiflexion in sitting• Subtalar abduction in sitting