ESPA

European Society of Anaesthesiology ESA

JOIN THE NEW EUROPEAN CLINICAL TRIAL

BLUEBERRY

Dexamethasone & postoperative bleeding following tonsillectomy in children

Double-blind, randomized, placebo control, multi-centre, pragmatic, Non-inferiority trial

Steering Committee

Prof. W. Habre (CH), Dr K. Becke (DE), Dr N. Disma (IT), Prof Th. Engelhardt, (CA), Prof Th. Erb (CH), Prof T Hansen (DK), Prof. C Höhne (DE), Dr M. Thomas (UK), Dr F. Veyckemans (FR), Mrs K. Virag (HU)

Medical Problem

Tonsillectomy is one of the most frequently performed surgical interventions in children in Europe. However, it is associated with a high incidence of PONV (PostOperative Nausea and Vomiting), severe pain and haemorrhage.

There is strong evidence on the efficacy of Dexamethasone in reducing the incidence of PONV and pain after tonsillectomy, which led to consider this drug as a first line treatment in routine anaesthesia practice in such surgical setting. However, in the last decade, there have been arguments about the potential role of Dexamethasone in increasing the risk of postoperative bleeding in children and studies addressing the haemorrhage risk following administration of Dexamethasone for tonsillectomy are inconclusive.

Thus, there is not enough evidence for the safety administration of Dexamethasone to control postoperative pain and prevent PONV following tonsillectomy.

Objective

Primary objective: To provide evidence of the Dexamethasone safety profile with regard to the risk of post-tonsillectomy bleeding in children when administered as a single intraoperative dose of 0.15mg/kg.

Secondary objective: to characterize whether the co-administration of NSAIDs for analgesia potentiates the risk of postoperative haemorrhage.

Outcomes

Primary endpoint:

- **Incidence of postoperative haemorrhage requiring re-operation within 30 days following tonsillectomy with or without adenoidectomy**

Secondary endpoints:

- Association between Dexamethasone use and increased/decreased incidence of Perioperative respiratory critical events, and PONV
- Pain scores and NSAIDs need during 7 days following surgery
- Morbidity and mortality at 30 days after surgery.

Study design

Double-blind (investigator-surgeon-patient blinded), randomized, placebo control, multi-centre, international, pragmatic, **Non-inferiority trial**

Inclusion Criteria

- Children aged from 2 to 16 years admitted for tonsillectomy/ tonsillotomy
- Parents or legal responsible person willing and capable to follow data collection by the **application (Android and iPhone) developed for this study**

Exclusion Criteria

Children with Congenital Heart Disease under Aspirin or any other anticoagulants
Children with any bleeding disorders (ex. Haemophilia, Von Willbrand Disease)

Procedures

Study product: Single intraoperative dose of Dexamethasone 0.15 mg/kg IV maximum 5 mg prepared by health provider not involved in the study
Control product: Single intraoperative dose of NaCl 0.9% IV

Measurements

- Postoperative period at hospital: assess occurrence of PONV, supplemental analgesia administration, and other postoperative events including bleeding
- 7 days follow-up by parents through the Application: daily pain score and NSAID administration
- 30 days follow-up through Application & Patient's medical record: Morbidity and mortality

Sample Size and Centres

3'794 children in total, 1'897 children in each treatment group. Sample size estimation is based on the definition of a minimal clinically important difference between the 2 groups of treatment to be equal to 2% (non-inferiority margin). We expect the involvement of 150 centres. The study is planned between 1st trimester 2020 to 1st trimester 2023.
The Application has been translated in 6 languages: English, French, German, Italian, Portuguese, Hungarian with additional translations foreseen: Spanish, Dutch, Danish,

How do you get involved?
Please contact by e-mail the Chief Investigator walid.habre@unige.ch or
Blueberry webmaster: blueberry@unige.ch

This study is endorsed by both the European Society for Paediatric Anaesthesia and the European Society of Anaesthesiology