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Do antibiotics help the child's recovery after partial tonsillectomy?

Submission date 05/05/2010	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 20/05/2010	**Overall study status** Completed	
Last Edited 20/05/2010	**Condition category** Oral Health	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Olaf Zagólski

Contact details
Dunin-W¹sowicza 20/II/3
Kraków
Poland
30-112

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
0001/2010

Study information

Scientific Title

Perioperative antibiotic therapy in adenoidectomy with partial tonsillectomy in children - prospective, interventional, double blinded, single centre, randomised study

Acronym
ABAT

Study objectives
Perioperative antibiotic prophylaxis may influence post-operative recovery in children in whom adenotonsillotomy is performed.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Bioethics Commission at the Regional Medical Chamber in Krakow (Komisja Bioetyczna przy Okręgowej Izbie Lekarskiej w Krakowie, Opinia) approved on the 23rd of Dec 2009 (ref: 178/KBL /iL/2009)

Study design
Prospective interventional double blinded single centre randomised crossover group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Adenoidal and tonsillar hyperplasia

Interventions
Curette adenoidectomy with scissors tonsillectomy. Oral administration of clindamycine prior to (one dose) and after (2 doses) the surgery.
The total duration of follow up for this trial will be 3 weeks.

The primary and secondary outcomes will be measured at 7, 14 and 21 post-operative days. The children's caregivers will fill a questionnare answering a standardised set of questions concerning the measures. the participants will be questioned about pain intensity using faces Pain Scale 1-10, the caregivers' satisfaction will be rated along 0-10 scale. Diet, physical activity and malorour from the mouth will be analysed according to the parent diary.

Joint sponsor:
Trialist will report results and any problems to the Bioethics Commission at the Regional Medical Chamber in Krakow (Komisja Bioetyczna przy Okręgowej Izbie Lekarskiej w Krakowie) on an annual basis

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Pain
2. Activity
3. Diet

Secondary outcome measures
1. Odour from the mouth
2. Parental satisfaction

Overall study start date
01/06/2010

Completion date
31/12/2010

Eligibility

Key inclusion criteria
1. Paediatric patients age 3-14
2. Indications for adenoidectomy with partial tonsillectomy
3. Hyperplasia of adenoid and palatine tonsils causing obstructive symptoms, identified from descriptions by the caregivers: snoring, gasping, choking as well as apnoeic episodes, and/or ear effusions

Participant type(s)
Patient

Age group
Child

Lower age limit
3 Years

Upper age limit
14 Years

Sex
Both

Target number of participants
120

Key exclusion criteria
1. Recurrent tonsillitis
2. Previous partial tonsillectomy for the symptoms enumerated above

Date of first enrolment
01/06/2010

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
Poland

Study participating centre
Dunin-W¹sowicza 20/II/3
Kraków
Poland
30-112

Sponsor information

Organisation
St. John Grande's Hospital (Poland)

Sponsor details
Day Surgery Department
Kraków
Poland
31-061

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
St. John Grande's Hospital (Poland) - Day Surgery Department

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration