

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

Submission date 05/05/2010	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/05/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 20/05/2010	Condition category Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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 questionnaire 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-W'sowicza 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