Antibiotica voor de behandeling van acute blindedarmontsteking bij kinderen.

Gepubliceerd: 15-03-2011 Laatst bijgewerkt: 18-08-2022

N/A

Ethische beoordeling	Niet van toepassing
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26391

Bron
NTR

Aandoening

Appendicitis
children
Antibiotic treatment
Non-operative treatment

Ondersteuning

Primaire sponsor: VU University Medical Center
Overige ondersteuning: VU University Medical Center

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Safety of initial antibiotic treatment defined as:
Occurrence of major complications, such as:
A. Anaphylactic shock and other allergic reaction to antibiotics administered
b. Recurrent appendicitis within 8 weeks

c. Recurrent appendicitis within one year after discharge
d. Development of perforated appendicitis
e. Occurrence of major complaints after delayed appendectomy such as intra-abdominal abscess (IAA), stumpleakage, superficial site infection (SSI), anaesthesia related complications, secondary bowel obstruction (SBO), re-admission, need for re-intervention
f. Re-admission
g. Re-intervention other than delayed appendectomy

Toelichting onderzoek

Achtergrond van het onderzoek

Appendectomy for acute appendicitis has recently been questioned as being the only correct treatment for appendicitis. Appendectomy has been reported to have significant early and late morbidity. This can be avoided with antibiotic treatment alone. Moreover, better quality of life and lower costs have been associated with antibiotic treatment alone. Five clinical trials in selected patients (males, older than 18 years) comparing appendectomy and antibiotic treatment alone as primary mode of treatment found that antibiotic treatment alone is safe and effective in 48-95% of the patients Conclusive evidence with regard to the efficacy of antibiotic treatment alone in children with proven acute appendicitis however is lacking. We propose a prospective cohort study to answer the following questions:

Primary research question:
What is the complication rate of the initial antibiotic treatment strategy (IATS) for acute simple appendicitis (radiological proven) in children aged 7-17 years old?

Secondary research question:
What is the complication rate of the direct appendectomy treatment strategy (DATS) for acute simple appendicitis (radiological proven) in children aged 7-17 years old?

Doel van het onderzoek

N/A

Onderzoeksopzet

1. Short term (1 month);

2. Long term (1 year).

A QOLquestionaire will be used for measurements.

Onderzoeksproduct en/of interventie

Initial antibiotic treatment strategy (IATS): Intravenous administration of amoxicillin/clavulanic acid 25/2.5mg 6-hourly (total 100/10 mg/kg daily; maximum 6000/600mg a day) and gentamicin 7mg/kg once daily will be given for 48 hours. If possible the antibiotics will be switched to oral amoxicillin/clavulanic acid 50/12.5 mg/kg 8-hourly (max 1500/375mg a day) for in total 7 days. If after 72 hours, the patient does not meet the predefined criteria, an appendectomy will be performed.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Age 7-17 years

• Radiologically confirmed simple appendicitis, defined as:

a. Clinical findings:

i. Unwell, but not generally ill

ii. Localized tenderness in the right iliac fossa region

iii. Normal/hyperactive bowel sounds

iv. No guarding

v. No mass palpable

b. Ultrasonography (see appendix 13.13):

i. Incompressible appendix with an outer diameter of ≥6 mm

ii. Hyperaemia within the appendiceal wall

iii. Without faecolith

iv. Infiltration of surrounding fat

v. No signs of perforation

vi. No signs of intra-abdominal abscess/phlegmone

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patients with severe general illness at time of presentation:

a. Generalized peritonitis defined as:

Diffuse inflammation of the peritoneum with clinical signs consisting of increasing abdominal pain, generalized tenderness, diffuse abdominal rigidity, sinus tachycardia, signs of paralytic ileus

b. Severe sepsis or septic shock, as defined by the international paediatric sepsis consensus conference [38]. (appendix 13.6)

c. Signs of complex appendicitis

2. Children with a faecolith on ultrasonography.

3. Patients with serious associated conditions or malformations such as:

a. Congenital or acquired cardiac or pulmonary disease with significant hemodynamic consequences

b. Immunodeficiency

c. Malignancy

d. Homozygous sickle cell disease

e. Metabolic disorders

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-06-2011
Aantal proefpersonen:	50
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2681
NTR-old	NTR2810
Ander register	Kinderchirurgisch Centrum Amsterdam : KCA2011
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A