De optimale behandelstrategie bij complexe blindedarmontsteking in kinderen

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Subgroup 1 (complex appendicitis without mass and/or abscess formation): LA is associated with reduced superficial site infections, shorter length of stay, less costs, less pain, and better hr-QoL, compared with OA without compromising overall…

Ethische beoordeling	Niet van toepassing
Status	Werving gestopt
Type aandoening	Maagdarmstelselinfecties
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26201

Bron
Nationaal Trial Register

Verkorte titel
CAPP study

Aandoening

- Maagdarmstelselinfecties

Aandoening

Acute complex appendicitis

Betreft onderzoek met
Mensen

Ondersteuning

Primaire sponsor: Amsterdam UMC

Secundaire sponsoren:	ZonMw
Overige ondersteuning:	ZonMw (Leading the Change)

Onderzoeksproduct en/of interventie

- Overige

Toelichting

Uitkomstmaten

Primaire uitkomstmaten

The proportion of patients experiencing any complication within 3 months after inclusion. All complications / events will be recorded and scored according to the Clavien-Dindo scale. The following events will be considered as complications but this list is not exhaustive: - Superficial Site infection: Criteria according to the CDC guidelines - Intra-abdominal abscess: Radiologically confirmed fluid collection containing pus or infected material that is surrounded by inflamed tissue. - Stump leakage / stump appendicitis: Radiologically confirmed intra-abdominal fluid collections after appendectomy / recurrence of disease after appendectomy. - Secondary / Prolonged bowel obstruction (including paralytic ileus): Patient requiring gastro-intestinal decompression with a nasogastric tube. - Anesthesia related complications (such as pneumonia) - Operation / trocar site hernia: Clinically confirmed by a resident or surgeon. - Need for additional surgical or radiological interventions related to primary disease (appendicitis) - Recurrent appendicitis: recurrence of disease within 3 months time after inclusion. - Re-admission for an indication related to appendicitis (such as readmissions for observation of fever and abdominal pain) All complications and their subsequent treatment will be registered.

Toelichting onderzoek

Achtergrond van het onderzoek

This is a nation-wide, multi-center, comparative, prospective cohort study with standardized treatments. Aim of this study is to evaluate the effect of different treatment strategies on overall complications, health related-Quality of Life (hr-QOL) and costs among two subtypes of complex appendicitis in children (<18 years old). Main research questions: What is the difference in overall complications at three months between: Subgroup 1 (complex appendicitis without abscess/mass formation): Laparoscopic (LA) and open appendectomy (OA) Subgroup 2: (complex appendicitis with abscess/mass formation): Non-operative treatment (NOT) and direct appendectomy

Doel van het onderzoek

Subgroup 1 (complex appendicitis without mass and/or abscess formation): LA is associated with reduced superficial site infections, shorter length of stay, less costs, less pain, and better hr-QoL, compared with OA without compromising overall complications. Subgroup 2 (complex appendicitis with mass and/or abscess formation): NOT is associated with reduced overall complications, shorter length of stay, better hr-QoL compared with direct appendectomy.

Onderzoeksopzet

Outcomes will be measured at the day of inclusion (= day 0), 3 days, 5 days, at discharge, 30 days, and 3 months after inclusion.

Onderzoeksproduct en/of interventie

Interventions: Subgroup 1: Laparoscopic appendectomy Subgroup 2: Non-operative treatment (consisting of intravenous antibiotics with or without (percutaneous) drainage procedure) Usual care/comparison (controls) Subgroup 1: Open appendectomy Subgroup 2: Direct appendectomy

Contactpersonen

Publiek

Emma Children's Hospital, Amsterdam UMC, Academisch Medisch Centrum & VU medisch centrum, Amsterdam, the Netherlands
Paul van Amstel

020-5665693

Wetenschappelijk

Emma Children's Hospital, Amsterdam UMC, Academisch Medisch Centrum & VU medisch centrum, Amsterdam, the Netherlands
Paul van Amstel

020-5665693

Deelname eisen

Leeftijd
Adolescenten (16-17 jaar)
Adolescenten (16-17 jaar)
Adolescenten (12-15 jaar)

Adolescenten (12-15 jaar)
Kinderen (2-11 jaar)
Kinderen (2-11 jaar)
Baby's en peuters (28 dagen - 23 maanden)
Baby's en peuters (28 dagen - 23 maanden)

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Eligible for inclusion are all children <18 years old that need to undergo treatment for the suspicion of complex appendicitis. Suspicion of complex appendicitis is based upon the following predefined criteria: - 4 or more points on our scoring system developed to predict complex appendicitis. This scoring system consists of five variables (clinical, biochemical and radiological, each awarded points). In case the total score is 4 or more points, the patient is likely to have complex appendicitis. Variables included in the scoring system are: - Diffuse abdominal guarding (3 points) - CRP level more than 38 mg/L (2 points) - Signs on ultrasound / imaging indicative for complex appendicitis (2 points) - More than one day abdominal pain (2 points) - Temperature more than 37.5 degrees Celsius (1 point) Or - High index of suspicion of complex appendicitis by the treating physician. If this is the case, the treating physician will make pre-treatment note upon what clinical, biochemical or radiological variable the high index of suspicion is based. Classification into the two subgroups of complex appendicitis will be based upon clinical and radiological features. If signs suggestive of perforated appendicitis AND intra-abdominal abscesses or enlarged mass formation are present, patients will be categorized as subgroup 2. If no abscess or enlarged mass is present on clinical exam and/or additional imaging, patients will be categorized as subgroup 1.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Adult patients (=18 years old) 2. Children with a suspicion of simple appendicitis (based upon the previous mentioned scoring system and radiological features)

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd

Controle:	N.v.t. / onbekend
Doel:	Behandeling / therapie

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	12-08-2019
Aantal proefpersonen:	1308
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	NL9371
Ander register	METC AMC : W18 302 # 18.348

Resultaten