Biological implants for the reconstruction of complex, contaminated abdominal wall defects.

Gepubliceerd: 26-04-2013 Laatst bijgewerkt: 18-08-2022

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24625

Bron
NTR

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome measure is the possible advantage of a biological mesh compared to the synthetic mesh, expressed in recurrence, morbidity, durability of the mesh (measured in the time passed postoperatively) and postoperative complications (measured in sepsis, reoperation and fistulation).

Toelichting onderzoek

Achtergrond van het onderzoek

Background: Approximately 2-24%% of the 100.000 laparotomy procedures performed in The Netherlands annually result in an incisional or abdominal wall hernia. Use of synthetic mesh is contra-indicated when the field is complicated, infected and/or contaminated because of the risk of adhesions, (chronic) sepsis and erosion. The results of the modern biological implants demonstrate that the biological grafts become recellularized and revascularized without being resorbed with fewer adhesions compared to synthetic meshes. Permacol, acellular porcine dermis, is the biological mesh of choice in Atrium Medical Centre Heerlen and Orbis Medical Centre Sittard.

Objective: A retrospective review of Atrium Medical Centre's in Heerlen and Orbis Medical Centre's in Sittard experience using Permacol for the repair of abdominal wall defects and a cost-effective analysis comparing the use of a synthetic mesh versus Permacol in complex abdominal wall hernia repair.

Methods: Retrospective review of medical records of patients undergoing abdominal wall reconstruction with Permacol compared with a case-matched control group in which a synthetic mesh has been used to determine the advantages and cost-effectiveness of the biological mesh.

Doel van het onderzoek

The use of a biological mesh in a contaminated/infected field is expected to have better outcomes on mortality, morbidity, performance, durability, postoperative complications and reoperations compared to use of a synthetic mesh. One of the explanations is because of their compliance with the host leukocyte response.

The costs of the more expensive biological implant weigh against the benefits of its use as explained above.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients with complex, contaminated wall defects, repaired with a biological mesh;

2. Patients with complex, contaminated wall defects, repaired with a synthetic mesh.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

N/A

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	26-04-2013
Aantal proefpersonen:	80
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	26-04-2013
Soort:	Eerste indiening

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	NL3799
NTR-old	NTR3972
Ander register	: 13-N-48
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A