Operative Vascular Intervention Decision-making Improvement Using SDM-tools

Gepubliceerd: 07-06-2017 Laatst bijgewerkt: 13-12-2022

Providing vascular surgical patients and vascular surgeons with decision support tools will improve the level of shared decision-making during consultation, increase disease-specific knowledge and quality of life and decrease decisional conflict.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21409

Bron
Nationaal Trial Register

Verkorte titel
OVIDIUS

Aandoening

Abdominal Aortic Aneurysm, Abdominaal Aorta Aneurysma, Intermittent Claudication, Etalagebenen, Varicose Veins, Spataderen, Shared Decision-Making, Gedeelde besluitvorming, Decision Support Tools, Keuzehulpmiddelen

Ondersteuning

Primaire sponsor: Academisch Medisch Centrum
Meibergdreef 9
1055 AZ AMSTERDAM ZUIDOOST
Overige ondersteuning: AMC Medical Research
Meibergdreef 9
1055 AZ AMSTERDAM ZUIDOOST

Stichting AMC Foundation

Postbus 22660
1100 DD AMSTERDAM ZUIDOOST

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The level of SDM during the doctor-patient consultations in which a treatment decision is to be made.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Previous studies show that the quality of patient care can be improved by using shared decision-making. Unfortunately, the use of shared decision-making is poor among vascular surgeons. Decision support tools are developed to assist vascular patients and their physicians in using SDM.

Objective: Our main objective is to improve the level of SDM during vascular surgical consultations in which a treatment decision is to be made, with the use of DSTs. Our secondary objectives are to improve SDM as experienced by both patients and physicians, patients' disease-specific knowledge and quality of life, a decrease in decisional conflict, a difference in chosen treatment, the successful introduction of DSTs and a cost-effectiveness study.

Study design: Our study design is a multicentre stepped-wedge cluster-randomised trial in 16 medical centres.

Study population: All adult patients, visiting the outpatient clinic of a participating vascular surgery department or vascular medical centre for whom several treatment options are feasible and who need to decide on a primary treatment of their abdominal aortic aneurysm, intermittent claudication or varicose veins, are eligible.

Intervention: Our study does not entail a (new) medicinal or surgical intervention. Patients and physicians in the intervention group are presented with decision support tools that will help them to use shared decision-making to make the final treatment decision. These decision support tools consist of a website that the patient can access to obtain information and that created awareness on the patients preferences with regard to the treatment options, and decision tables or cards that physicians can use to determine which aspect of a treatment is most important to their patient. In addition, the physicians are provided a training session about shared decision-making and the use of decision support tools.

Main study parameters/endpoints: The level of shared decision-making during consultation scored objectively by independent observers on audio-recording with the use of the 5-item OPTION instrument.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Patients in the intervention group are required to invest their time to use the decision aid and consider their preferences. Previously discovered benefits for patients are improved quality of care, enhanced patient satisfaction and therapy adherence. It also, prevents undesired care and a reduction in patient opting for major treatments. The use of decision support tools or shared decision-making shows no adverse effects on health outcomes.

Doel van het onderzoek

Providing vascular surgical patients and vascular surgeons with decision support tools will improve the level of shared decision-making during consultation, increase disease-specific knowledge and quality of life and decrease decisional conflict.

Onderzoeksopzet

• Baseline (before consultation)

• During consultation

• Directly after consultation

• 4 weeks after consultation or just before endovascular or open surgical treatment

• 6 weeks after treatment.

Onderzoeksproduct en/of interventie

Decision support tools: Decision Aids, Decision Tables, Decision Cards, Training

Contactpersonen

Publiek

Meibergdreef 9

Sylvana de Mik
Academisch Medisch Centrum, Kamer G4-140

Amsterdam 1055 AZ
The Netherlands
+31 (0)20 566 2971

Wetenschappelijk

Meibergdreef 9

Sylvana de Mik
Academisch Medisch Centrum, Kamer G4-140

Amsterdam 1055 AZ
The Netherlands
+31 (0)20 566 2971

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Age ≥ 18 years

• Newly diagnosed patients with an asymptomatic AAA and which has grown to 5,5 cm or more.

• Newly diagnosed patients with invalidating IC (Fontaine IIb)

• VV for which the patient is considering treatment

• Eligible for more than one treatment option

• Written informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Insufficient understanding of the Dutch language or cognitively unable to complete Dutch questionnaires.

• Life expectancy less than 1 year

• Patients requiring emergency surgery

• ASA IV patients

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2018
Aantal proefpersonen:	376
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	07-06-2017

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	NL6312
NTR-old	NTR6487
Ander register	AMR project code : 18954/SB157001

Resultaten

Samenvatting resultaten
N/A