Assessment of patient preference of follow-up in cardiac stent trials

Gepubliceerd: 26-06-2014 Laatst bijgewerkt: 18-08-2022

To investigate whether patients prefer to be approached by mailed questionnaires for annual follow-up assessment after PCI procedures versus telephone interviews or email-based follow-up

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

Samenvatting

ID

NL-OMON22823

Bron
NTR

Verkorte titel
PAPAYA Study

Aandoening

Patient preference, follow-up, percutaneous coronary intervention, TWENTE trial, DUTCH PEERS trial

Ondersteuning

Primaire sponsor: Cardio Research Enschede (CRE), Thoraxcentrum Twente, Medisch Spectrum Twente, Enschede, The Netherlands
Overige ondersteuning: Investigator initiated study without particular funding

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

In current clinical practice there is a increasing demand for real-world evidence to guide public health and clinical decision-making, therefore the patient-centered research approach will be an integral part of future research endeavors. Collaboration between health care workers and patients will thus play an increasing role in future research. To improve this professional relationship it is important to assess patients preferences since patient satisfaction is an important element in evaluating the quality of health care services from the patient's perspective and in predicting how patients will behave after receiving services. Although there are a few patient preference studies on therapy, data is still lacking in how patients prefer to be followed-up There is no data on patients preference on follow-up and how they prefer to be contacted when included in stent trials.

Objective:

To investigate the patient preference of approach to obtain follow-up information after percutaneous coronary intervention (PCI)

Study design:

Single-center, prospective, observational registry

Study population:

All patients enrolled in the percutaneous coronary intervention (PCI) studies TWENTE trial (a broad study population reflecting real-world PCI patients) and DUTCH PEERS trial (an all-comers population), who were treated at Thoraxcentrum Twente in Enschede between June 2008 and May 2012

Intervention:

All subjects will receive a questionnaire with questions regarding their preference with regards of the approach of acquiring follow-up information after PCI

Main study endpoints:

- The primary endpoint is the patient preference on how to be approached for annual follow-up after PCI procedures.

- Secondary endpoints include (1) least preferred approach of follow up, (2) the preferred number of follow-up moments per year, (3) the from the patient's perspective maximum acceptable number of questions to be answered, (4) the assessment of potential relationships between the most and least preferred approach of assessment and patient age, gender, urgency of PCI treatment, and history of previous revascularizations

Doel van het onderzoek

To investigate whether patients prefer to be approached by mailed questionnaires for annual follow-up assessment after PCI procedures versus telephone interviews or email-based follow-up

Onderzoeksopzet

Questionnaires were sent once to the patients home address

Onderzoeksproduct en/of interventie

All subjects will receive a questionnaire with questions regarding their preference with regards of the approach of acquiring follow-up information after PCI.

Patient and procedural characteristics of non-responders were compared to responders.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

All patients enrolled in the percutaneous coronary intervention (PCI) studies TWENTE trial (a broad study population reflecting real-world PCI patients) and DUTCH PEERS trial (an all-comers population), who were treated at Thoraxcentrum Twente in Enschede between June 2008 and May 2012

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients who had withdrawn their consent for participation in the TWENTE and DUTCH PEERS trials, respectively. Patients who passed away during follow-up could obviously not be approached for further questioning

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Enkelblind

Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	04-07-2013
Aantal proefpersonen:	2550
Type:	Onbekend

Ethische beoordeling

Positief advies

Datum:	26-06-2014
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	NL4521
NTR-old	NTR4656
Ander register	METC MST : K13-28

Resultaten

Samenvatting resultaten
N/A