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

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22823

Source
Nationaal Trial Register

Brief title
PAPAYA Study

Health condition

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

Sponsors and support

Primary sponsor: Cardio Research Enschede (CRE), Thoraxcentrum Twente, Medisch Spectrum Twente, Enschede, The Netherlands
Source(s) of monetary or material Support: Investigator initiated study without particular funding

Intervention

Outcome measures

Primary outcome

Assessment of preferred approach for annual follow-up after PCI

Secondary outcome

- Least preferred approach for follow up

- Relation between most and least preferred approach of assessment in relation to age, gender, urgency of PCI treatment, history of previous revascularization

Study description

Background summary

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

Study objective

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

Study design

Questionnaires were sent once to the patients home address

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	04-07-2013
Enrollment:	2550
Type:	Unknown

Ethics review

Positive opinion

Date:	26-06-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4521
NTR-old	NTR4656
Other	METC MST : K13-28

Study results

Summary results

N/A