Assessment of the ‘Managing Advanced Cancer Pain Together’ (MACPT) tool to facilitate communication on total cancer pain between advanced cancer patients and their healthcare professionals (20160376)

First published: 19/10/2018

Last updated: 19/02/2021

Study Finalised

Administrative details

EU PAS number

EUPAS25858

Study ID

39584

DARWIN EU® study

No

Study countries

France

Germany

United Kingdom

Study description

The research focus is the assessment of a paper based conversation tool, the ‘Managing Advanced Cancer Pain Together’ (MACPT) conversation tool, developed to support a comprehensive pain dialogue between the patient and healthcare practitioner (HCP) during their routine face-to-face consultation.

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 27/03/2026

Institution

Multiple centres: 4 centres are involved in the study

Contact details

Study institution contact

Global Development Leader Amgen Inc.

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Study contact

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Primary lead investigator

Global Development Leader Amgen Inc.

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 29/05/2017

Study start date

Planned: 31/01/2019

Actual: 04/01/2019

Data analysis start date

Planned: 01/06/2021

Actual: 18/12/2020

Date of final study report

Planned: 02/03/2021

Actual: 19/02/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

20160376_01.02.06 Public Redacted Protocol Ver 1.0 English.pdf (399.04 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Patient survey

Data collection methods:

Primary data collection

Main study objective:

The overall objective of this study is to assess the MACPT conversation tool, developed to support a comprehensive pain dialogue between advanced cancer patients and their HCPs during their routine face-to-face consultation.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Short-term pre-post study design

Study drug and medical condition

Medical condition to be studied

Cancer pain

Population studied

Short description of the study population

Advanced cancer patients.

- Age 18 years or older
- A diagnosis with one of the following primary cancer type: breast cancer, prostate cancer, lung cancer or multiple myeloma
- A record of stage IV, metastatic status, distant spread, or bone pain due to cancer metastases/bone lesion(s), specifically:

o Patients with breast cancer must be diagnosed with advanced or metastatic disease.

o Patients with prostate cancer must have a nodal or metastatic condition.

o Patients with lung cancer must have stage IIIB or stage IV non-small cell lung cancer or advanced small cell lung cancer.

o Patients with multiple myeloma

- Ability to read, write and understand English, French or German (in accordance with the site he/she has been recruited from)
- Sufficient capabilities to participate in the study (as assessed by the HCP)
- No significant difficulty with hearing, reading or speaking
- No diagnosed memory impairment

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Special population of interest

Other

Special population of interest, other

Cancer patients

Estimated number of subjects

200

Study design details

Outcomes

To assess the impact of the MACPT tool on patient- and HCP- reported overall satisfaction score (as measured using the patient- and HCP versions of the satisfaction questionnaire) of their conversation during face-to-face routine standard-of-care (SoC) consultations. To assess the impact of the MACPT tool on patient and HCP reported satisfaction score. To describe the frequency of the tool words selected by the patients as a proxy for elucidating the themes or components of total cancer pain. To assess the usefulness of the MACPT conversation tool in helping HCPs identify key aspects of the patient’s total pain experience.

Data analysis plan

The analytic focus will be on pre- and post- MACPT tool exposure.The primary analysis will entail comparing the mean change in patient reported overall satisfaction scores of their conversation during face-to-face routine standard-of-care consultations before and after use of the MACPT tool, a paired t-test will assess if the mean change differs from zero. The mean change in HCP-reported overall satisfaction score before and after use of the MACPT tool will also be compared in the same manner, and treated as a co-primary endpoint.The secondary analyses include comparing the mean change in patient- and HCP-reported satisfaction score on specific aspects of their conversation during face-to-face routine standard-of-care (SoC) consultations, calculating the frequency

and percentage of patients selecting each pain descriptor of the MACPT tool. Both patient and HCP’s responses to the brief questionnaire on the MACPT tool’s usefulness will also be descriptively summarized.

Documents

Study results

01.47.01.01 Observational Research Study Report Published Report (5)_Redacted.pdf (237.36 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No