A Global Cross-sectional Survey to Capture Awareness and Knowledge of Mesenchymal Stem Cell (MSC) Therapy by Gastroenterologists and Colorectal Surgeons

First published: 10/12/2019

Last updated: 16/02/2024

Study Finalised

Administrative details

EU PAS number

EUPAS31926

Study ID

44354

DARWIN EU® study

No

Study countries

Australia

Austria

Canada
Denmark
France
Germany
Israel
Italy
Japan
Korea, Republic of
Netherlands
Spain
Switzerland
United Kingdom
United States

Study description

This study is an observational, multinational, cross-sectional cohort study. This study will be assessed by means of a study specific online survey designed to describe current perspectives, awareness, and knowledge of MSC therapy amongst gastroenterologists and colorectal surgeons. All the eligible physicians would be asked to fill a web-based survey which would be containing approximately 37 multiple choice questions related to sociodemographic variables and study outcomes. The survey would take approximately 15 minutes to complete. This study will collect the data via Qualtrics, web-based survey platform, and via email at a single time point. The study will enroll approximately 387 physicians. The study will be conducted in 15 countries. The overall duration of the survey will be approximately 15 months.

Study status

Finalised

Research institutions and networks

Institutions

IQVIA

United Kingdom

First published: 12/11/2021

Last updated: 22/04/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

Dimitri Bennett trialdisclosures@takeda.com

Study contact

trialdisclosures@takeda.com

Primary lead investigator

Rachele Ciccocioppo

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 20/01/2019

Actual: 28/01/2019

Study start date
Planned: 01/09/2020

Actual: 07/05/2020

Data analysis start date
Planned: 01/12/2020

Actual: 01/12/2020

Date of final study report
Planned: 01/03/2021

Actual: 18/03/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda

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:

Other

Study topic, other:

Disease/Epidemiology study

Study type:

Non-interventional study

Scope of the study:

Other

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

Knowledge and attitudes

Data collection methods:

Primary data collection

Main study objective:

To quantitatively describe current perspectives, awareness, and current knowledge state (including knowledge about mechanism of action) of MSC therapy amongst gastroenterologists and colorectal surgeons.

Study Design

Non-interventional study design

Cross-sectional

Population studied

Short description of the study population

Study participants were gastroenterologists and colorectal surgeons identified using IQVIA’s proprietary comprehensive database containing investigator specialty and contact details for physicians that are involved in research but also physicians not involved in research. In total, 387 gastroenterologists and colorectal surgeons were targeted to be enrolled in 15 countries'. Sampling per country was weighted to reflect estimates of prevalence of CD per country and country population size and efforts were made to ensure recruitment from different sites and from each type of institution, to increase generalizability of findings.

Inclusion criteria:

• Physicians must be currently practicing registered gastroenterologists or colorectal surgeons and

• Physicians must be practicing within one of the in-scope countries

Exclusion criteria

• There were no specific exclusion criteria for this survey.

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)

Estimated number of subjects

387

Study design details

Outcomes

Primary outcome will include the quantitative description of the sociodemographic and clinical experience characteristics, level of awareness, and current knowledge of MSCs amongst gastroenterologists and colorectal surgeons by type of institution and geographic regions worldwide, their main concerns related to MSC application, and the willingness to use MSC therapy in clinical practice setting.

Data analysis plan

Descriptive statistics and/or listings will be used. Continuous variables will be summarized by number of participants n, mean, standard deviation, median, minimum, maximum, first quartile, and third quartile. Categorical variables will be summarized by n and percentage of participants in each category. Missing data will not be imputed, and all analyses will be based on participants with no missing data only.

Documents

Study results

Alofisel-5006_Study Report_ MSC Survey_Takeda_V1.0_18Mar2021.pdf (2.39 MB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Other

Data sources (types), other

Study participants will consist of gastroenterologists and colorectal surgeons identified using IQVIA’s proprietary comprehensive database that contains investigator specialty and contact details for physicians that are involved in research but also physicians not involved in research. Multiple sources would be combined with some internal to IQVIA and some external sources.

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