Regional differences in hemodialysis practices, treatment strategies and patient outcomes over time in Turkey: A Multicenter Observational Cohort Study in Turkish Hemodialysis Patients (20150316)

First published: 06/03/2017

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Study Ongoing

Administrative details

EU PAS number

EUPAS18090

Study ID

18091

DARWIN EU® study

No

Study countries

Türkiye

Study description

This observational study aims to describe regional differences by focusing on real-life HD practices, treatment strategies and patient outcomes of all-cause mortality and cardiovascular morbidity in relation with treatment strategies over time in the clinical management of Turkish dialysis patients to improve standardization in HD practices and treatment strategies for patients receiving HD in Turkey.

Study status

Ongoing

Research institutions and networks

Institutions

Ankara Üniversitesi

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Institution

Tıp Fakültesi Ibn-i Sina Hastanesi,Nefroloji Bilim Dalı

İstanbul Bilim Üniversitesi Tıp Fakültesi, Nefroloji Bilim Dalı İstanbul, Baskent Üniversitesi Ankara

Hastanesi, Nefroloji Bilim Dalı Ankara, Hacettepe Üniversitesi Tıp Fakültesi, Nefroloji Bilim Dalı Ankara, Gazi Universitesi Tip Fakultesi, Nefroloji Anabilim Dalı Ankara, Özel Gaziosmanpaşa Yaşam Diyaliz Merkezi İstanbul, Ultra Diyaliz Merkezi İstanbul, Özel Ataşehir Diyaliz Merkezi İstanbul, Özel Merzifon Diyaliz Merkezi Amasya, Özel Keçiören Diyaliz Merkezi Ankara, Özel Nefrogrup Diyaliz Merkezi Ankara

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Kenan Ates

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/09/2016

Actual: 23/09/2016

Study start date
Planned: 30/11/2016

Actual: 27/01/2017

Data analysis start date
Planned: 30/11/2016

Date of interim report, if expected
Planned: 27/07/2018

Date of final study report
Planned: 05/02/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen İlaç Tic. Ltd. Şti.

Study protocol

20150316_StudyOutline_V2_ENG_dd20161201.pdf (177.8 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 type:

Non-interventional study

Scope of the study:

Disease epidemiology

Main study objective:

To define differences in patient outcomes in relation with treatment strategies in different regions of Turkey.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

End stage renal disease

Population studied

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

2500

Study design details

Outcomes

The rate of patient all cause mortality and cardiovascular morbidity in differentregions of Turkey in relation with treatment stragies. The rate of patient all-cause mortality and cardiovascular morbidity in different regions of Turkey in relation with HD practices.The rate of hospitalizations and infections in different regions of Turkey.The difference in Hb levels in incident and prevalent HD patients in different regions of Turkey.Hb concentrations in relation with dialysis vintage, age and gender.

Data analysis plan

This study is descriptive.Only summary statistics and interval estimates will be provided.The number of clinical outcomes per subject will be tallied.Normal

approximation 95% confidence intervals(CI) will be computed around the proportion estimates. The rate of mortality and morbidity will be calculated as the number of clinical outcomes or death divided by the duration on study.Poisson CI will be computed around the rate estimate. The proportions, rates and CI will be computed for the whole study population and for subgroups defined by treatment. The secondary outcomes will assess the proportions and rates from the primary outcome by geographic regions. Regions will be defined both by HD practice and bySHPT parameters.

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

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