Effectiveness and Safety of Enoxaparin: Higher versus Standard Dose for Thromboprophylaxis in Patients of Varying Body Mass Index – A Retrospective Observational Cohort Study Using Real World EHR and Claims Data

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Study Ongoing

Administrative details

EU PAS number

EUPAS43864

Study ID

48855

DARWIN EU® study

No

Study countries

Finland

Study description

Obesity is associated with an increased risk of venous thromboembolism (VTE) events. Hospitalized patients have an 8-fold increased risk of VTE, where obesity, surgery and medical acute illness are important, contributing factors. The risk of VTE is also increased among patients undergoing bariatric and non-bariatric surgeries. While enoxaparin is a common therapy for VTE prophylaxis among medically ill and surgical patients, the understanding of an appropriate dosing and duration of the therapy for obese patients is limited. This is an observational, retrospective, cohort study in Finland including patients hospitalized with an acute medical illness or undergoing bariatric or non-bariatric surgery, receiving enoxaparin treatment for VTE prophylaxis from 1 May 2008 to 31 December 2020. The primary objective is to evaluate the impact of higher as compared with standard daily dose of enoxaparin on the risk of VTE and major bleeding events (MBE) at 3-months (primary effectiveness and safety endpoints) in hospitalized medically ill patients and in surgical patients (bariatric and non-bariatric settings). The impact will be analyzed for varying categories of BMI, including obese patients. The secondary objective 1 is to evaluate the impact of higher as compared with standard daily dose of enoxaparin on the risk of VTE and MBE among obese patients, in strata of patient and treatment characteristics: medical or surgical setting, age, sex, history of VTE, history of MBE, treatment duration of enoxaparin prophylaxis, enoxaparin dosing schedule, and surgery type (for surgical patients only). The secondary objective 2 is to evaluate the impact of daily dose of enoxaparin in combination with pre-specified patients and treatment characteristics by using cluster analysis, on the risk of VTE and MBE, separately in hospitalized medically ill and surgical patients.

Study status

Ongoing

Research institutions and networks

Institutions

IQVIA

United Kingdom

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Institution **Non-Pharmaceutical company** **ENCePP partner**

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Arnaud Mickael

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 08/10/2020

Actual: 08/10/2020

Study start date
Planned: 01/10/2021

Actual: 11/04/2022

Data analysis start date
Planned: 23/05/2023

Date of final study report
Planned: 30/04/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Sanofi

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

Protocol ID CEF0034

Methodological aspects

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Main study objective:

To evaluate the impact of higher as compared with standard daily dose of enoxaparin on the risk of VTE and MBE at 3-months (primary effectiveness and safety endpoints) in hospitalized medically ill patients and in surgical patients (bariatric and non-bariatric settings).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(B01AB05) enoxaparin

enoxaparin

Medical condition to be studied

Thrombosis prophylaxis

Obesity

Additional medical condition(s)

Venous thromboembolism prophylaxis in medically ill patients and moderate to high risk surgical patients including obese patients

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

72.000

Study design details

Outcomes

The risk of VTE and MBE at 3-months, 1. Risk of VTE and MBE in obese patients treated with higher versus standard daily dose of enoxaparin, in strata of medical or surgical setting, age, sex, VTE history, MBE history, treatment duration, dosing schedule, and surgery type. 2. Impact of daily dose of in pre-specified patients by cluster analysis, on VTE and MBE risks, separately in hospitalized medically ill and in surgical patients.

Data analysis plan

Primary objective: Patients treated with higher and standard daily dose of enoxaparin will be matched on propensity score (PS). Kaplan- Meier method will be used to compare the time to the first outcomes between the cohorts. Cox

proportional hazards regression will be used to estimate the hazard ratio (with 95% confidence intervals) for time to VTE and MBE. Covariates included in the PS that are unbalanced after the PS-matching will be candidate covariates for adjustment in the Cox model. The analyses will be stratified by BMI category. Sensitivity analyses will be performed. Secondary objective 1 will be analyzed as for the primary objective, exclusively among obese patients and using the patient and treatment characteristics as stratification variables. Secondary objective 2 will use cluster analysis to identify patient clusters in medically ill and surgical patients separately. The relationship between identified patient cluster memberships with VTE and MBE will be analyzed.

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 source(s), other

Finnish National registries: Care Register for Health Care, Register of Primary Health Care Visits, Prescription Registers, Causes of Death Register, and Population Information System Finland, Finnish electronic medical record: the hospital districts of Helsinki and Uusimaa and the hospital district of Southwest

Finland Finland

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

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