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Eptinezumab for the acute treatment of status migraine

Submission date
31/10/2025

Recruitment status
Recruiting

Registration date
04/11/2025

Overall study status
Ongoing

Last Edited
17/07/2026

Condition category
Nervous System Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Migraines are a frequent reason for emergency department (ED) visits due to the significant disability they cause and the associated symptoms such as nausea, vomiting, dehydration, and hypersensitivity to light and sound. The current standard of care in Quebec hospitals includes intravenous hydration and administration of an intravenous antiemetic, usually metoclopramide, a non-specific migraine treatment that often causes side effects, including drowsiness, dizziness, and akathisia. As a result, patients often spend several hours in the ED before experiencing relief; few patients report complete relief at discharge, and one in four return for unresolved or recurrent migraine.

The recent introduction of monoclonal antibodies targeting the calcitonin gene-related peptide (CGRP) represents a major advancement in migraine management. This is the first class of medications specifically designed for the disease. Four anti-CGRP agents are currently approved and publicly reimbursed in Quebec for migraine prevention: galcanezumab, fremanezumab, atogepant, and eptinezumab. Eptinezumab is the only preventive agent that has also demonstrated a rapid onset of action in clinical trials. However, its effectiveness has not yet been studied for treating severe and prolonged migraine attacks in patients presenting to the emergency department.

The study hypothesis is that the dual action of eptinezumab, both acute and preventive, could significantly improve migraine relief and associated symptoms in the ED. It is also anticipated that there will be a reduction in the frequency of migraine attacks during the three months following the emergency visit, due to eptinezumab's previously demonstrated preventive effect.

Who can participate?
Adults aged 18 years and over who have at least 4 migraine days per month.

What does the study involve?
This is a prospective, interventional, single-center study to evaluate the effectiveness of eptinezumab for the treatment of status migrainosus when administered in the ED of a community hospital (St. Mary's Hospital). All patients will be offered follow-up at the tertiary headache center of the Montreal University Health Center (CHUM). A telephone follow-up will

be done 1 week after discharge from the ED to increase study retention and monitor for drug adverse events.

What are the possible benefits and risks of participating?
Benefits and risks not provided at time of registration

Where is the study run from?
All patients will be followed up at the tertiary headache center of the Centre Hospitalier de l' Université de Montréal (CHUM).

When is the study starting and how long is it expected to run for?
July 2026 to April 2027

Who is funding the study?
H. Lundbeck A/S (Denmark)

Who is the main contact?
Marzieh Eghtesadi, marzieh.eghtesadi.med@ssss.gouv.qc.ca

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Marzieh Eghtesadi

ORCID ID
https://orcid.org/0000-0003-0409-0421

Contact details
CHUM 1000 St Denis
Montreal
Canada
H2X0C1
+1 5148908000
marzieh.eghtesadi@mail.mcgill.ca

Additional identifiers

Study information

Scientific Title
Eptinezumab for the acute treatment of status migrainosus in the emergency department of a community hospital

Acronym
ED-RELIEF

Study objectives

To evaluate the effectiveness of eptinezumab for the acute treatment of status migrainosus in the emergency department.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 30/07/2025, Research Center of the Montreal University Health Center (CHUM - Pavillon R 900, rue St-Denis, Montreal, H2X 0A9, Canada; +1-514-890-8000; soutien.rc.chum@ssss.gouv.qc.ca), ref: MP-02-2026-13088

Primary study design
Interventional

Study design
Interventional single-center prospective unblinded study

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Migraine

Interventions
Patients presenting to the Emergency Department at St Mary's Hospital with a migraine attack lasting more than 72 hours will receive a single 300 mg intravenous dose of eptinezumab over 30 minutes. Criteria related to acute migraine relief will be assessed using the Questionnaire to be completed by the ED physician, administered by emergency physicians. Patients will be advised to document their migraine frequency using the Canadian Migraine Tracker and evaluated 12 weeks after the infusion at the tertiary headache clinic of the Montreal University Health Center for the study's secondary outcomes related to eptinezumab's preventative effect, so that it may be represcribed by the physician if beneficial to the patient after completing a provincial reimbursement formulary.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Eptinezumab (Vypeti)

Primary outcome(s)
Current primary outcome as of 01/06/2026:
1. Percentage of patients reporting pain relief from status migrainosus measured using a four-point intensity scale at T+120 (120 minutes post-infusion)

Previous primary outcomes:
1. Percentage of patients reporting pain relief from status migrainosus measured using a four-point intensity scale at T+120 (120 minutes post-infusion)

2. Percentage of patients reporting the absence of their most bothersome associated symptom of status migrainosus measured using a yes/no questionnaire at T+120

Key secondary outcome(s)

Current secondary outcomes as of 01/06/2026:
1. Percentage of patients reporting complete pain freedom measured using a four-point intensity scale at T+120
2. Perceived improvement measured using the Patient Global Impression of Change (PGIC) scale at T+120
3. Percentage of patients receiving a rescue migraine treatment measured using the patient's chart in the pharmacological profile section between T+120 and medical discharge from ED
4. Number of patients requiring a neurology consultation in the emergency department measured using the patient's chart in the medical observations section at one timepoint
5. Percentage of patients reporting a ≥50% reduction from baseline in the number of monthly migraine days (MMDs) measured using the application Canadian Migraine Tracker by the Canadian Headache Society, averaged over Weeks 1 through 12
6. Perceived improvement measured using the Patient Global Impression of Change (PGIC) scale at 12 weeks following eptinezumab infusion
7. Migraine interictal burden score measured using the Migraine Interictal Burden Scale (MIBS-4) questionnaire at baseline and 12 weeks following eptinezumab infusion
8. Number of patients returning to the emergency department for migraine within 12 weeks following eptinezumab infusion, measured using data collected from patient medical records at one timepoint
9. Percentage of patients reporting the absence of their most bothersome associated symptom of status migrainosus measured using a yes/no questionnaire at T+120
10. Consent rate, proportion of participants receiving the complete infusion, adherence to procedures in the emergency department, data completeness, retention rate at follow-up and recruitment speed, measured using reporting from clinical staff and chart review on day 1 of emergency department visit and T12weeks post infusion
11. Reasons for refusal or interruption measured using feedback from clinical staff and an acceptability questionnaire on day 1 of emergency department visit
12. Frequency, nature and severity of adverse events, infusion reactions and hypersensitivity reactions measured using patient self-reporting, clinical staff reporting and chart review from onset of infusion until visit T12 weeks post-infusion

Previous secondary outcomes:
1. Percentage of patients reporting complete pain freedom measured using a four-point intensity scale at T+120
2. Perceived improvement measured using the Patient Global Impression of Change (PGIC) scale at T+120
3. Percentage of patients receiving a rescue migraine treatment measured using the patient's chart in the pharmacological profile section between T+120 and medical discharge from ED
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7. Migraine interictal burden score measured using the Migraine Interictal Burden Scale (MIBS-4) questionnaire at baseline and 12 weeks following eptinezumab infusion

8. Number of patients returning to the emergency department for migraine within 12 weeks following eptinezumab infusion, measured using data collected from patient medical records at one timepoint

Completion date
01/04/2027

Eligibility

Key inclusion criteria
Current inclusion criteria as of 29/05/2026:
1. Adults over 18 years of age with at least 4 monthly migraine days, who present to the emergency department for a migraine attack lasting more than 72 hours
2. Pain reported by the patient (on a numeric scale 0 to 10) ≥ 6 out of 10
3. Patient who speaks and understands English or French

Previous inclusion criteria:
1. Adults over 18 years of age
2. At least 4 monthly migraine days
3. Who present to the emergency department with a migraine attack lasting more than 72 hours

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
99 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
Current exclusion criteria as of 29/05/2026:
1. Contraindications to eptinezumab according to the product monograph
2. Current pregnancy, breastfeeding, or plans to become pregnant within the next 5 months
3. Treatment with Botox or another anti-CGRP therapy (galcanezumab, erenumab, fremanezumab, atogepant, eptinezumab) within the past year
4. Uncontrolled cardiovascular risk factors or active cardiovascular disease (hypertension, diabetes, Raynaud’s phenomenon, cerebrovascular accident, cardiomyopathy, myocardial

infarction)
5. Uncontrolled psychiatric illness
6. Immunodeficiency
7. Autoimmune disease
8. Return visits for patients already enrolled in the study

Previous exclusion criteria:
1. Contraindications to eptinezumab as per the product monograph
2. Current pregnancy, breastfeeding, or planned pregnancy within the next 5 months
3. Preventive treatment received within the past year: onabotulinumtoxinA or another anti-CGRP agent
4. Uncontrolled cardiovascular risk factors or active cardiovascular disease (ischemic heart disease, angina, recent stroke)
5. Raynaud’s disease

Date of first enrolment
27/07/2026

Date of final enrolment
01/12/2026

Locations

Countries of recruitment
Canada

Study participating centre
Montreal University Health Center
1000, rue St-Denis
Montreal
Canada
H2X 0C1

Study participating centre
St Mary's Hospital
3830 Av. Lacombe
Montreal
Canada
H3T 0A2

Sponsor information

Organisation
Centre Hospitalier de l’Université de Montréal

ROR
https://ror.org/0410a8y51

Funder(s)

Funder type
Industry

Funder Name
H. Lundbeck A/S

Alternative Name(s)
Lundbeck

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Denmark

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analyzed during the current study will be published as a supplement to the results publication.

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files			04/11/2025	No	No