A retrospective case report series of patients (post-marketing) Receiving Olanzapine IntraMuscular Outside of Product Monograph doses and indications: assessing safety and tolerability

Submission date	Recruitment status No longer recruiting	Prospectively registered		
25/06/2006		☐ Protocol		
Registration date 31/08/2006	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	[] Individual participant data		
07/01/2021	Mental and Behavioural Disorders			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

R-06-127

Study information

Scientific Title

A retrospective case report series of patients (post-marketing) Receiving Olanzapine IntraMuscular Outside of Product Monograph doses and indications: assessing safety and tolerability

Acronym

ROIMOPM

Study objectives

To review safety and tolerability of olanzapine intramuscular (IM) used outside of product monograph dosing and indications.

Ethics approval required

Old ethics approval format

Ethics approval(s)

University of Western Ontario Heath Research Ethics Board (Ref: 12254E, case number R-06-127).

Study design

Observational retrospective case report series

Primary study design

Observational

Secondary study design

Other

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Various mental disorders under Diagnostic and Statistical Manual of mental disorders fourth edition (DSM-IV)

Interventions

The intervention will be based on clinicians observations where the included patients have recieved Olanzapine IM.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Olanzapine intramuscular

Primary outcome measure

Risk/benefit assessment of olanzapine IM being used in the included patients.

Secondary outcome measures

Demographics and concurrent medications resulting in therapeutic issues (post-marketing surveillance).

Overall study start date

01/07/2006

Completion date

31/12/2007

Eligibility

Key inclusion criteria

Patients whom have received Olanzapine IM in doses exceeding doses stated in literature or for uses not listed in the current edition of the Compendium of Pharmaceuticals and Specialties.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

аррх 10

Total final enrolment

8

Key exclusion criteria

Patients under 16 or over 70 years of age, or those whom have a documented allergy or sensitivity to olanzapine, also patients whom have used the olanzapine IM within normal dosing parameters.

Date of first enrolment

01/07/2006

Date of final enrolment

31/12/2007

Locations

Countries of recruitment

Canada

Study participating centre 375 South Street

London Canada N6A 4G5

Sponsor information

Organisation

London Health Sciences Centre (Canada)

Sponsor details

375 South Street Room S117 London Canada N6A 4G5

Sponsor type

Hospital/treatment centre

Website

http://www.lhsc.on.ca/

ROR

https://ror.org/037tz0e16

Funder(s)

Funder type

Industry

Funder Name

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2011	07/01/2021	Yes	No