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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	[ ] Prospectively registered
25/06/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
31/08/2006	Completed	[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

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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
appx 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
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N6A 4G5

Sponsor information

Organisation
London Health Sciences Centre (Canada)

Sponsor details
375 South Street
Room S117
London
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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

Eli Lilly Canada (Canada)

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