

Cases Count: 4

Case Number: 233683

Data Entry Date: 21/09/2007 Weight (kg): 0

Hospitalisation: Age:

DOB: 06/05/1981 **Onset Date:**

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity **Report Description**

Treatment

Gender: M

Blood creatine phosphokinase

increased

Caused or prolonged inpatient

hospitalisation

Creatine kinase high, ecg abnormal, Tachycardia, White blood cell count

increased and neutrophils increased.

Electrocardiogram abnormal Caused or prolonged

inpatient

hospitalisation

Caused or prolonged Neutrophil count increased

> inpatient hospitalisation

Caused or prolonged Tachycardia

> inpatient hospitalisation

White blood cell count

increased

Caused or prolonged

inpatient hospitalisation

Medicine details:

AMISULPRIDE (Suspected) Reason:

Started: 21/12/2005 Stopped: Batch:

PIMOZIDE (Suspected) Reason:

Batch: Started: Stopped:

QUETIAPINE (Suspected) Reason:

Batch: Started: Stopped:

Laboratory Investigations:

Type Range Date Tested Result Details

Creatine 28 Mar 2006 - CK ranged from 621 -

phosphokinase 728 (ref 0 - 270)

Electrocardiography ECG on 5 May 2006 showed increased sinus rate of approximately 115 bpm.

Pulse varied from 87 - 122 bpm.

White blood cells WBC ranged from 11.5 - 17.7 x 10^9/L

(ref 4.0 - 11.0)

PUTRAN02 Page 1 of 5 **Laboratory Investigations:**

Туре Range Date Tested Result Details

Neutrophils were 13.00 x 10^9/L (ref 1.8 - 7.5) Neutrophils

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Cases Count: 4

Gender: F

Case Number: 240602

Data Entry Date: 05/05/2008 **Weight (kg)**: 0

Hospitalisation: Required a visit to the doctor **Age**: 99u

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Suicidal ideation Patient experienced severe

depression and extreme suicidal thoughts over the last 3 to 4 weeks. Also experienced hyeractivity and was unable to sleep.

Depression Insomnia

Psychomotor hyperactivity

Medicine details:

CORTISONE (Suspected) Reason :

Injection

Batch: 7FL6000 exp:06/12. Started: Stopped:

ORAP (Suspected) Reason :

Tablet 32 Milligram Daily Oral

Batch: 8CL1200 exp: 01/20 Started: Stopped:

TEGRETOL (Other drug) Reason :

Oral

Batch: Started: Stopped:

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Cases Count: 4

Case Number : 246263

Hospitalisation: Hospitalisation prolonged **Age**: 78Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Recovered

Information:

Reaction: **Preferred Term** Severity **Report Description Treatment** Torsade de pointes Lit report: Post=fall fracture Bag and valve mask ventilation of tibia and fibula. Deuring was commenced and 10 mL of closed reduction, for which magnesium sulfate 10% propofol was administered solution was administered. as sedation, the patient had an episode of Torsade de pointes/polymorphic ventricular tachycardia (VT) lasting 30 s, followed by 10 s of ventricular

fibrillation (VF).

Medicine details: **IMIPRAMINE HYDROCHLORIDE (Suspected)** Reason: 75 Milligram Oral Batch: Started: Stopped: PROPOFOL (Suspected) Reason: 40 Milligram Total Intravenous Batch: Started: Stopped: 0 THIORIDAZINE HYDROCHLORIDE (Suspected) Reason: 25 Milligram Daily Batch: Started: Stopped: **MORPHINE HYDROCHLORIDE (Other drug)** Reason: 12.5 Milligram Daily Intravenous Batch: Started: Stopped: 0 TRAMADOL HYDROCHLORIDE (Other drug) Reason: 200 Milligram Stopped: Batch: Started:

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Cases Count: 4

Case Number: 248289

Hospitalisation: Age: 78Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Recovered

Information: Past medical history: included depression, osteorarthritis and chronic lymphocytic

leukaemia. Literature Data;

Douglas R, CadogenM, Cardiac arrhythmia during propofol sedation. Emergency

Medicine Australasia 2008 Oct;20(5):437-440.

Reaction:

Preferred Term Severity Report Description Treatment

Torsade de pointes

During cast placement, the patient suffered an episode of torsades de ventricular

tachycardia (VT) lasting 30 seconds, followed by 10 seconds of ventricular

fibrillation (VF).

Bag and Valve mask ventilation was commenced and 10ml of

magnesium sulfate 10% solution was administered IV. There was spontaneous return

of cardiac output.

Cardiopulmonary resuscitation

was not required.

Ventricular fibrillation Ventricular tachycardia

Batch:

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PROPOFOL (Suspected) Reason:

Intravenous

THIORIDAZINE HYDROCHLORIDE (Suspected) Reason :

Started:

Intravenous

Stopped:

Batch: Started: Stopped:

IMIPRAMINE HYDROCHLORIDE (Other drug) Reason :

Batch: Started: Stopped:

Laboratory Investigations:

Type Range Date Tested Result Details

Other data Venous blood gas immediatley after the

event revealed no electrolyte disturbance. A subsequent ECG demonstrated normal sinus rhythm at rate of 72 b.p.m. with QTc of 405 ms. There was no evidence of ishaemic

change.

Selection Parameters: Date Range: 01/08/2007 To 31/12/2059 Unclear causality excluded GM medicines Only Medicine Names: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE, ANATENSOL, ANATENSOL ENANTHATE FOR INJECTION, FLUPHENAZINE DECANOATE, FLUPHENAZINE ENANTHATE, FLUPHENAZINE HYDROCHLORIDE, FLUPHENAZINE NOS, MODECATE, ALDAZINE, MELLERIL, THIORIDAZINE HYDROCHLORIDE, NEULACTIL, PERICYAZINE, PIMOZIDE, ORAP

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