# A study to compare the safety and efficacy of durogesic with sustained release morphine in patients with cancer pain transferring from weak to strong opioids

Submission date	Recruitment status No longer recruiting	Prospectively registered		
19/08/2002		☐ Protocol		
Registration date 19/08/2002	Overall study status Completed	Statistical analysis plan		
		[X] Results		
<b>Last Edited</b> 26/03/2020	Condition category Signs and Symptoms	[] Individual participant data		

#### Plain English summary of protocol

Not provided at time of registration

#### Contact information

#### Type(s)

Scientific

#### Contact name

Dr - -

#### Contact details

UKCCCR Register Co-ordinator MRC Clinical Trials Unit 222 Euston Road London United Kingdom NW1 2DA

## Additional identifiers

Protocol serial number

FEN-INT-15

# Study information

Scientific Title

A Study to Compare the Safety and Efficacy of Durogesic with Sustained Release Morphine in Patients with Cancer Pain Transferring from Weak to Strong Opioids

#### **Study objectives**

Not provided at time of registration

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Not provided at time of registration

#### Study design

Randomised controlled trial

#### Primary study design

Interventional

#### Study type(s)

**Not Specified** 

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

Cancer pain

#### **Interventions**

Patients are randomised to one of two treatment arms:

- 1. Arm A: Durogesic (transdermal fentanyl) commencing at 25  $\mu$ g/h with rescue analgesia as needed.
- 2. Arm B: Sustained release morphine commencing at 30 mg twice daily with rescue analgesia as needed.

#### Intervention Type

Drug

#### Phase

**Not Specified** 

#### Drug/device/biological/vaccine name(s)

fentanyl, morphine

#### Primary outcome(s)

Not provided at time of registration

#### Key secondary outcome(s))

Not provided at time of registration

#### Completion date

31/12/1999

# **Eligibility**

#### Key inclusion criteria

- 1. Aged over 18 years old
- 2. Histologically, radiologically or haematologically confirmed malignancy, whose pain is judged by the investigator to be caused by the malignancy
- 3. Patients whose pain has reached a stage now requiring treatment with a strong opioid
- 4. Patients who have received a regular weak opioid, for at least 48 hours and at a dosage appropriate for their pain at that time
- 5. Not previously received regular treatment with a strong opioid for their cancer pain. This should have not exceeded more than three doses of a strong immediate release opioid in the last 7 days, and none in the last 24 h
- 6. No planned treatment within the next 24 h which may alter abruptly the degree or nature of pain experienced
- 7. No current or planned cytotoxic chemotherapy
- 8. No medical contraindications to protocol treatment

#### Participant type(s)

Patient

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Sex

**Not Specified** 

#### Key exclusion criteria

Does not meet inclusion criteria

#### Date of first enrolment

01/01/1997

#### Date of final enrolment

31/12/1999

## Locations

#### Countries of recruitment

United Kingdom

England

#### Study participating centre

#### UKCCCR Register Co-ordinator London United Kingdom NW1 2DA

# Sponsor information

#### Organisation

Janssen-Cilag Ltd (UK)

#### **ROR**

https://ror.org/03qwpn290

# Funder(s)

#### Funder type

Industry

#### Funder Name

Janssen-Cilag Ltd (UK)

# **Results and Publications**

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	01/05/1997	26/03/2020	Yes	No