

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 19/08/2002	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 19/08/2002	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 26/03/2020	Condition category Signs and Symptoms	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr - -

Contact details

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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

Primary study design

Interventional

Study design

Randomised controlled trial

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 µg/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/03qwpm290>

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