

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
		<input type="checkbox"/> Protocol
Registration date 19/08/2002	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 26/03/2020	Condition category Signs and Symptoms	<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

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

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

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 measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/1997

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

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Target number of participants

Not provided at time of registration

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

England

United Kingdom

Study participating centre

UKCCCR Register Co-ordinator

London

United Kingdom

NW1 2DA

Sponsor information

Organisation

Janssen-Cilag Ltd (UK)

Sponsor details

Saunderton

High Wycombe

United Kingdom

HP14 4HJ

Sponsor type

Industry

Website

<http://www.janssen-cilag.co.uk>

ROR

<https://ror.org/03qwpn290>

Funder(s)

Funder type

Industry

Funder Name

Janssen-Cilag Ltd (UK)

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