ISRCTN34797860 https://doi.org/10.1186/ISRCTN34797860

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	[_] Prospectively registered [_] Protocol
Registration date 19/08/2002	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 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
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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