A Multicentre, Open-Label, Extension Study to Investigate the Safety and Efficacy of AD 923 (Fentanyl Sublingual for the Treatment of Breakthrough Cancer Pain in Subjects with Malignicies

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To obtain more information about the efficacy and tolerability of AD 923 in long-term management of breakthrough pain in subjects with malignicies who are taking a stable dose of background opioids and receive therapy for BTP.

Ethical review	Approved WMO
Status	Pending
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON32098

Source
ToetsingOnline

Brief title
P-AD923-006 extension study

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
Breakthrough Cancer Pain

Research involving
Human

Sponsors and support

Primary sponsor: i3 Research
Source(s) of monetary or material Support: Sosei R & D Ltd

Intervention

Keyword: AD 923 (fentanyl sublingual), Breakthrough Cancer Pain, sublingual spray

Outcome measures

Primary outcome

to assess the safety and tolerability of AD 923

AD 923 sublingual

to show the usually rapid relief of pain with AD 923

physical examination including vital signs

laboratory assessments

assessment of mucositis

Secondary outcome

not applicable

Study description

Background summary

Title of the study

A study to see if AD 923 (fentanyl sprayed under the tongue) works and is safe in patients with uncontrolled pain due to cancer.

Sosei R&D Ltd. has begun a research study of an investigational drug called AD 923 (fentanyl sublingual) for the possible treatment of breakthrough pain in patients with cancer (protocol P-AD923-005). This study is a follw-up and patients who completed the first study are eligible to participate in this open-label study. AD 923 in this study will not be compared with another medicine.

Both the subject as the investigator knows the study drug will be given with a specified dose per subject.

Fentanyl is a potent opioid that has been in clinical use for many years in anaesthesia and for the treatment of pain and is approved by the Food and Drug Administration (FDA) and in Europe for different ways of administration. The active ingredient of AD 923 is fentanyl, but sublingual (under the tongue) delivery is not registered yet.

Previous studies have shown that AD 923 may relieve breakthrough pain in patients with cancer and that pain relief was usually rapid. In terms of benifits, safe, effective, easily administered treatment is needed for BTP in patients with malignicies where the onset of pain is typically very quick. Additionally, the mode of delivery, including the option for administration by a caregiver, has the potential to overcome some of the problems faced by this population, including difficulty in swallowing or lack of dexterity.

Study objective

To obtain more information about the efficacy and tolerability of AD 923 in long-term management of breakthrough pain in subjects with malignicies who are taking a stable dose of background opioids and receive therapy for BTP.

Study design

A multicentre, open-label, extension study of the safety and efficacy of AD 923. Both subject and investigator knows that study drug is given in a subject specific dose.

Intervention

AD 923 (fentanyl sublingual) in doses 200-1200 µg per episode of breakthrough pain

Study burden and risks

Baseline Visit
1. assess inclusion and exclusion criteria
2. review medical history
3. record concomitant and rescue medications
4. record AEs
5. perform physical examination
6. perform mucositis assessment
7. record vital signs
8. perform urine pregnancy test for all women of childbearing potential
9. administer 12-lead ECG

10. administer HADS and BQP
11. draw blood for routine clinical laboratory tests
Study Visit 9-11 will be a weekly telephone contact
Visit 12-14
1. record concomitant and rescue medications
2. assess disease status
3. record vital signs
4. record AEs
5. perform mucositis assessment
6. review diary and confirm diary connectivity and operation
7. dispense study drug
8. study drug reconciliation
9. at study visit 13, a blood draw for routine clinical laboratory tests
Visit 15, End of Treatment
1. record concomitant and rescue medications
2. assess disease status
3. perform physical examination
4. perform mucositis assessment
5. record vital signs
6. draw blood for routine clinical laboratory and urine pregnancy test for all women of childbearing potential
7. administer 12-lead ECG
8. administer HADS and BQP
9. record AEs
10. collect diary
11. collect all study supplies including unused study drug
12. study drug reconciliation

Contacts

Public
i3 Research

Gevers Deynootweg 93L
2586 BK, Den Haag
Nederland
Scientific
i3 Research

Gevers Deynootweg 93L
2586 BK, Den Haag
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. subject completed study protocol P-AD923-005
2. subject met all eligible criteria for protocol P-AD923-005
3. subject continues to take opioid therapy for chronic cancer pain and continues to require therapy for episodes of BTP, minimun dose of background therapy should be 60 mg/day of morphine or morphine equivalent or 25 µg/hour transdermal fentanyl
4. if female of chilbearing potential, the subject has a negative urine pregnancy test
5. subject is able and willing to understand the study and cooperate with the study instructions
6. subject is able and willing to provide written informed consent
7. subject has a life expectancy of at least 2 months
8. subject or his or her caregiver must have easy, reliable access to a telephone

Exclusion criteria

1. The subject is a female who is pregnant or lactating.
2. The subject has developed any respiratory or cardiac condition that may be worsened by opiates.
3. The subject has developed any allergy to the product excipients, namely, fentanyl, ethanol, menthol, or saccharin.
4. The subject has developed any neurologic or psychiatric disease that, in the opinion of the investigator, would compromise data collection.
5. The subject has begun to abuse alcohol or other substance(s).
6. The subject has hepatic dysfunction as shown by alanine aminotransferase (ALT) and / or aspartate aminotransferase (AST) levels elevated more than 5 times the upper limit of normal.
7. The subject has renal dysfunction as shown by creatinine elevated more than 1.5 times the upper limit of normal.

8. The subject has any other clinically significant abnormality in the laboratory tests that, in the opinion of the investigator, will compromise the conduct of the study.
9. The subject has uncontrolled infection.
10. The subject is taking intrathecal or epidural forms of opioids.
11. The subject is taking any prohibited medications as described in the concomitant medications section (Section 6.3).

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	19-12-2007
Enrollment:	33
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Does not yet exist
Generic name:	Sublingual Fentanyl Spray
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	05-11-2007
Application type:	First submission

Review commission: METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2007-000559-32-NL
CCMO	NL20166.028.07