ISRCTN10634411 https://doi.org/10.1186/ISRCTN10634411

Study on initial pain management in patients with acute pancreatitis

Submission date	Recruitment status	[_] Prospectively registered
27/04/2023	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
11/05/2023	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
11/05/2023	Signs and Symptoms	[_] Record updated in last year

Plain English Summary

Background and study aims
Abdominal pain is the main symptom for most patients with acute pancreatitis (AP). It's important for diagnosing AP and can affect the patient's prognosis. Early management of AP involves pain relief and fluids, but there is debate on the best pain relief protocol. Pain is a big part of the patient's experience and relieving it can improve their quality of life and lower the risk of complications.

Previous studies have not shown a clear favourite among analgesic drugs for AP. A new review of 12 randomized control trials found that epidural analgesia was most effective for pain relief in the first 24 hours, but opioids were just as effective at 48 hours. Non-steroidal anti-inflammatory drugs (NSAIDs) were just as effective as opioids for pain relief in the first 24 hours. However, the studies had limitations and were not able to determine the specific efficacy of each analgesic drug.

Opioids are still the main treatment for pain in AP, but they have side effects like constipation and slow digestion. Recent studies have shown that opioids can worsen AP. Despite the importance of pain relief in AP, there have been few well-designed studies on analgesic protocols, and guidelines for managing AP do not offer clear recommendations.

This study aims to document current analgesic practices for AP in the UK and examine the relationship between analgesics and complications of AP.

Who can participate?
Adults over 18 years, at the first visit to a hospital for acute pancreatitis.

What does the study involve?
This is an observational study looking at patient records, no additional activity is being carried out with participants.

What are the possible benefits and risks of participating?
None

Where is the study run from?
Freeman Hospital (UK)

When is the study starting and how long is it expected to run for?

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Sanjay Pandanaboyana, s.pandanaboyana@nhs.net

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Multicentre prospective study on initial PAin management IN patients with Acute Pancreatitis: PAINAP study protocol

Acronym
PAINAP

Study hypothesis
The PAINAP Study aims to determine current analgesic practices and association between type of analgesic use and their impact on short term outcomes in patients with AP

Ethics approval required
Old ethics approval format

Ethics approval(s)
This is prospective observational study. The study was registered with Newcastle hospitals NHS Trust R&D department. The R&D department agreed that given the prospective nature of the study and there is no patient identifiable information, formal ethics approval is not required.

Study design
Multicentre prospective observational study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital, University/medical school/dental school

Study type(s)
Treatment

Participant information sheet
Not applicable (study uses existing data)

Condition
Pain management in acute pancreatitis

Interventions
There will be no change in the clinical course for the participants in this trial given this is a observational study. The patients will be followed for 1 month post recruitment to record any complications.
Patient records will be used to:
1. Document current analgesic practice for patients with Acute pancreatitis
2. Examine the relationship between different analgesics and local and systemic complications of AP.

Intervention Type
Other

Primary outcome measure

Analgesics used during admission (i.e. simple analgesics, mild opioids, strong opioids and epidural analgesia) are measured using patient records at a single time point.

Secondary outcome measures
Local and systemic complications of AP measured using patient records at a single time point (one month after admission)

Overall study start date
01/04/2022

Overall study end date
30/06/2022

Eligibility

Participant inclusion criteria
1. Patients aged 18 years and above
2. First presentation with acute pancreatitis of any etiology

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1,000

Total final enrolment
2200

Participant exclusion criteria
1. Recurrent acute pancreatitis
2. Chronic pancreatitis
3. Post ERCP pancreatitis (will have been given prophylactic NSAIDs)
4. Those on regular opioids, trycyclic antodipressaants and gabapentinoids for other painful conditions, including chronic pain (for other reasons)
5. Pregnancy

Recruitment start date
01/04/2022

Recruitment end date

30/06/2022

Locations

Countries of recruitment

Argentina

Australia

China

Cyprus

Denmark

Egypt

England

Georgia

Greece

India

Italy

Jordan

Kyrgyzstan

New Zealand

Pakistan

Portugal

Romania

Scotland

Serbia

Singapore

South Africa

Spain

Sri Lanka

Sudan

Türkiye

Ukraine

United Kingdom

United States of America

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Sponsor information

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Sponsor type
Hospital/treatment centre

Website
http://www.newcastle-hospitals.org.uk/hospitals/freeman-hospital.aspx

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Manuscripts are currently under preparation. Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/08/2023

Individual participant data (IPD) sharing plan

The datasets generated during and analysed during the current study are/will be available upon request from Mr Sanjay Pandanaboyana, s.pandanaboyana@nhs.net

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 2	23/02/2022	28/04/2023	No	No