Study on initial pain management in patients with acute pancreatitis

Submission date	Recruitment status No longer recruiting	Prospectively registered		
27/04/2023		[X] Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
11/05/2023		[X] Results		
Last Edited 09/06/2025	Condition category Signs and Symptoms	[] Individual participant data		
0710012023				

Plain English summary of protocol

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

Contact name

Mr Sanjay Pandanaboyana

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Contact details

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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 objectives

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)

Health condition(s) or problem(s) studied

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 timepoint

Secondary outcome measures

Local and systemic complications of AP measured using patient records at a single timepoint (1 month after admission)

Overall study start date

01/04/2022

Completion date

30/06/2022

Eligibility

Key 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

Key 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

Date of first enrolment

01/04/2022

Date of final enrolment

Argentina

Australia

China

Cyprus

Sudan

Locations

Countries of recruitment

Denmark Egypt England Georgia Greece India Italy Jordan Kyrgyzstan New Zealand Pakistan Portugal Romania Scotland Serbia Singapore South Africa Spain Sri Lanka

Türkiye

Ukraine

United Kingdom

United States of America

Wales

Study participating centre The Newcastle upon Tyne Hospitals NHS Foundation Trust

Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Study participating centre

University Hospital Southampton NHS Foundation Trust

Southampton General Hospital Tremona Road Southampton United Kingdom SO16 6YD

Study participating centre

Nottingham University Hospitals NHS Trust - City Campus

Nottingham City Hospital Hucknall Road Nottingham United Kingdom NG5 1PB

Study participating centre South Tyneside & Sunderland NHS Ft Sun

Sunderlandchildrenscentre Durham Road Sunderland United Kingdom SR3 4AG

Study participating centre James Cook University Hospital Laboratory

James Cook University Hospital Marton Road Middlesbrough United Kingdom TS4 3BW

Study participating centre

University Hospitals Birmingham NHS Foundation Trust - Oxford Covid19 Trials

Queen Elizabeth Hospital Edgbaston Birmingham United Kingdom B15 2TH

Study participating centre Glasgow Royal Infirmary

84 Castle Street Glasgow United Kingdom G4 0SF

Study participating centre Northern Health

185 Cooper St Melbourne Australia VIC 3076

Study participating centre Logan Hospital

Loganlea Road Meadowbrook Australia QLD 4131

Study participating centre

Royal Melbourne Hospital

300 Grattan Street Melbourne Australia VIC 3050

Study participating centre Royal North Shore Hospital

Reserve Road St Leonards Australia NSW 2065

Study participating centre Prince of Wales Hospital

Lui Che Woo Clinical Sciences Building (Professorial Block), Ngan Shing St, Sha Tin Hong Kong China 999077

Study participating centre Barking, Havering and Redbridge University Hospitals

4 Lyon Road Romford United Kingdom RM1 2BA

Study participating centre East Suffolk and North Essex

100 Mansbrook Blvd Ipswitch United Kingdom IP3 9GJ

Study participating centre East Surrey Hospital

Canada Avenue Redhill United Kingdom RH1 5RH

Study participating centre Frimley Park Hospital Laboratory

Frimley Park Hospital Portsmouth Road Frimley Camberley United Kingdom GU16 7UJ

Study participating centre James Paget University Hospital

Lowestoft Road Gorleston Great Yarmouth United Kingdom NR31 6LA

Study participating centre Leicester General Hospital

Gwendolen Road Leicester United Kingdom LE5 4PW

Study participating centre Manchester Royal Infirmary Laboratory

Manchester Royal Infirmary Oxford Road Manchester United Kingdom M13 9WL

Study participating centre Musgrove Park Hospital (taunton)

Musgrove Park Hospital Taunton United Kingdom TA1 5DA

Study participating centre North Bristol NHS Trust

Southmead Hospital Southmead Road Westbury-on-trym Bristol United Kingdom BS10 5NB

Study participating centre Northumbria Specialist Emergency Care Hospital

Northumbria Way Cramlington United Kingdom NE23 6NZ

Study participating centre Northwick Park and St Marks NHS Trust

Northwick Park Hospital Watford Road Harrow United Kingdom HA1 3UJ

Study participating centre University Hospitals Plymouth NHS Trust

Derriford Hospital Derriford Road Derriford Plymouth United Kingdom PL6 8DH

Study participating centre Gateshead - Queen Elizabeth Hospital

Queen Elizabeth Hospital Sherriff Hill Gateshead United Kingdom NE9 6SX

Study participating centre Royal Devon and Exeter Hospital NHS Trust - Novavax Covid19 Trial

Royal Devon & Exeter Hospital Barrack Road Exeter United Kingdom EX2 5DW

Study participating centre University Hospitals Bristol and Weston NHS Foundation Trust

Trust Headquarters Marlborough Street Bristol United Kingdom BS1 3NU

Study participating centre Wexham Park Hospital

Wexham Street Wexham Slough United Kingdom SL2 4HL

Study participating centre Whittington Health NHS Trust

The Whittington Hospital Magdala Avenue London United Kingdom N19 5NF

Study participating centre Tbilisi State Medical University

33 Vazha Pshavela Ave Tbilisi Georgia 0186

Study participating centre

Agnelli Hospital in Pinerolo

Via Brigata Cagliari Pinerolo Italy 10064

Study participating centre ASST Monza - San Gerado Hospital

Via G. B. Pergolesi Monza Italy 20900

Study participating centre Azioenda Policlinico San Marco

Corso Europa Zingonia Italy 24040

Study participating centre

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Via Ferdinando Palasciano Caserta Italy 81100

Study participating centre Hospital San Paolo

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Study participating centre Istuto Clinico Sant' Ambrogio

Via Cristina Belgioioso Milan Italy 20157

Study participating centre Lorenzo Bonomo Hospital Andria

Viale Istria Andria Italy 70031

Study participating centre Ospedale SS Trinità-ASL Cagliari

Via Is Mirrionis Cagliari Italy 09121

Study participating centre Treviso Regional Hospital

Piazzale dell'Ospedale Treviso Italy 31100

Study participating centre University of Cagliari

Via Università Cagliari Italy 09124

Study participating centre University of Pisa

Lungarno Antonio Pacinotti Pisa

Study participating centre Auckland City Hospital

2 Park Road, Grafton Auckland New Zealand 1023

Study participating centre Canturbury District Health Board

28 Elizabeth Street Ashburton New Zealand 7700

Study participating centre Hospital Garcia de Orta

Av. Torrado da Silva Almada Portugal 2805-267

Study participating centre Dumfries & Galloway Royal Infirmary

Cargenbridge Dumfries Dumfries and Galloway United Kingdom DG2 8RX

Study participating centre Royal Infirmary of Edinburgh at Little France

51 Little France Crescent
Old Dalkeith Road
Edinburgh
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United Kingdom
EH16 4SA

Study participating centre National University Hospital

5 Lower Kent Ridge Rd Singapore Singapore 119074

Study participating centre Chris Hani Baragwanath Academic Hospital

26 Chris Hani Rd, Diepkloof 319-Iq Johannesburg South Africa 1864

Study participating centre Hospital Clinico Universitario Valladolid

Av. Ramón y Cajal, 3 Valladolid Spain 47003

Study participating centre Hosptial Universitation Principe de Asturias

Carretera de Alcalá, s/n Madrid Spain 28805

Study participating centre University of Pittsburg Medical Centre

200 Meyran Ave Pittsburgh United States of America 15231

Study participating centre Cardiff and Vale UHB

Health Park Cardiff United Kingdom CF14 4XW

Study participating centre DACIM Foundation

Arenales 1640 Buenos Aires Argentina C1061AAT CABA

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37 Guoxue Ln, Wuhou District, Chengdu Sichuan China 610041

Study participating centre Zagzig University

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Study participating centre Aristotle University of Thessalonika

Thessalonika 541 24, Greece Thessalonika Greece 541 24

Study participating centre Laikon General Hospital

Agiou Thoma 17, Athina Athens Greece 115 27

Study participating centre

University Hospital of Heraklion

Leof. Panepistimiou Iraklio Greece 715 00

Study participating centre University of Patras

Πανεπιστημιούπολη Πατρών Greece 265 04

Study participating centre

Hyderabad

Hyderabad India 500032

Study participating centre

Maulana Azad Medical College & Lok Nayak Hospital

2, Bahadur Shah Zafar Marg, near Delhi Gate, Maulana Azad Medical College Campus, Balmiki Basti New Dehli India 110002

Study participating centre

Post Graduate Institute of Medical Education and Research Chandigarh

Madhya Marg, Sector 12 Chandigarh India 160012

Study participating centre AOU G Marinak, Policlinic of Messina

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Study participating centre Cattinara University Hospital

Strada di Fiume, 447 Trieste Italy 34149

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Via Enrico Russo, 11 Naples Italy 80147

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Rome Italy 00185

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Study participating centre Vimercate Hospital

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Study participating centre Vito Fazzi Hospital Leece

Piazza Filippo Muratore, 1 Leece Italy 73100

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Study participating centre Dr Ziuauddin University Hospital

Karachi Port Trust Hospital, Plot No. 33, Behind Kemari Karachi City Pakistan 75600

Study participating centre Liquiat University of Medical and Health Sciences

C7PC+337 Jamshoro Pakistan 76090

Study participating centre Mayo Hospital

Hospital Rd, Anarkali Bazaar Lahore Pakistan 54000

Study participating centre Bagdasar Arseni Emergency Hospital

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Study participating centre UMC Zvezdara, Belgrade

Dimitrija Tucovića 161 Belgrade Serbia 11160

Study participating centre Complejo Hospitalario Universitario de Vigo

Estrada de Clara Campoamor, 341 Vigo Spain 36312

Study participating centre Hospital Universitario de Cabuenes

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B229 Hospital Rd Dehiwala-Mount Lavinia, Sri Lanka 10350

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JH62+FPW Khartoum Sudan JH62+FPW

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Study participating centre Bukovinian State Medical University

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Study participating centre Regional Emergency Hospital

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Study participating centre The Guys and Lewisham NHS Trust

Guys Hospital St Thomas Street London United Kingdom SE1 9RT

Study participating centre Centro Hospitalar do Tâmega e Sousa

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Study participating centre Evaggelismos General Hospital

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Study participating centre Mater Hospital

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Study participating centre Aberdeen Royal Infirmary

Foresterhill Road Aberdeen United Kingdom AB25 2ZN

Study participating centre Mercy University Hospital

Grenville Pl, Centre Cork United Kingdom T12 WE28

Study participating centre Chesterfield Royal Hospital NHS Foundation Trust

Chesterfield Road Calow Chesterfield United Kingdom S44 5BL

Study participating centre Leeds Teaching Hospitals NHS Trust

St. James's University Hospital Beckett Street Leeds United Kingdom LS9 7TF

Study participating centre Asian Institute of Medical Sciences (AIMS) Hospital Hyderabad Pakistan 121001

Study participating centre Aosta Valley

Via Ginevra, 3 Aosta Italy 11100

Study participating centre County Durham and Darlington NHT Foundation Trust

Hollyhurst Rd Darlington United Kingdom DL3 6HX

Study participating centre Larnaka General Hospital

Pandoras Larnaca Cyprus 6301

Study participating centre Sandwell and West Birmingham Hospitals NHS Trust

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Study participating centre Royal Berkshire Hospital Royal Berkshire Hospital

London Road Reading United Kingdom RG1 5AN

Study participating centre San Raffaele Scientific Institute, Vita Salute San Raffaele University

Via Olgettina, 58 Milan Italy 20132

Study participating centre Jordan University Hospital

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Study participating centre University Hospital Lewisham

Lewisham High Street London United Kingdom SE13 6LH

Study participating centre East Lancashire Hospitals NHS Trust

Casterton Ave Burnley United Kingdom BB10 2PQ

Study participating centre

All India Institute of Medical Sciences Rishikesh

Virbhadra Road Shivaji Nagar, near Barrage, Sturida Colony Rishikesh India 249203

Sponsor information

Organisation

Newcastle upon Tyne Hospitals NHS Foundation Trust

Sponsor details

Newcastle Joint Research Office 1st Floor Regent Point Regent Farm Road Gosforth Newcastle upon Tyne England United Kingdom NE3 3HD +44 1912448005 aaron.jackson@nhs.net

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?
<u>Protocol file</u>	version 2	23/02/2022	28/04/2023	No	No
Results article		14/08/2024	09/06/2025	Yes	No