1. Screening and consent at local trial centre

Patient Screening (local trial centre)

- Out patient clinic
- Patient register
- At discharge or FU after admission

Patient info sheet



- In research clinic/unit
- Discussion and questions
- Confirmation of eligibility
- Signing of consent
- Baseline clinical data collection
- Trial number given
- Entered onto trial register
- Confirmation of pain protocol
- Instructions about procedure for contact and randomization if in crisis

2. Initial phone triage at Local Trial Centre (consented participant phoning-in with APC)

Patient contacts Local Trial Centre

- Use of specific telephone number/mobile
- Call taken by trial nurse/administrator
- Brief history and triage according to standard questionnaire

Symptoms

Mild pain or other mild symptoms

Uncomplicated pain crisis with severe pain

Symptoms of complicated crisis

Triage Algorithm by trial nurse of doctor







Triage decision

Phone advice +/referral to GP or community
No randomization

Verbal confirmation of consent **Eligible for randomization**

ED for urgent care
No randomization

3. Subject eligible for randomization

Randomization and further procedure at Local Trial Centre

Local trial team confirm unable to randomize



Observation arm

- Implement standard care
- CRF for APC episode
- CFR's Day 14 and 28



randomization

ACU bed and/or care team not available

- Trial team not available
- Timing does not allow 6 hours of ACU care



Local trial team confirm able to randomize

- Confirmation ED and ACU care available
- Trial staff available
- Timing allows 6 hours of ACU care

Randomization and further procedures over phone

- On-line randomization
- Inform patient of treatment location
- Inform care team of patient pending arrival
- Care team prepare pain protocol and prescriptions
- Trial team take baseline data

4. Trial procedure after arrival of randomized patient in ED or ACD

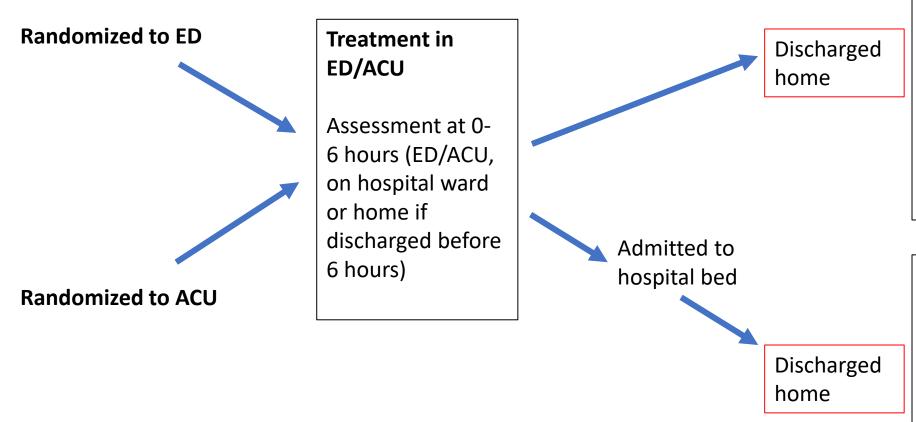
Arrival in ED or ACU

- Baseline observationsstandard care
- Clinical assessment-standard care
- Pain management protocolstandard care
- VAS pain scores- collected by trial team hourly for first 6 hours (potentially using app)
- Vital signs hourly for first 6 hours- standard care

Assessment at 6 hours (ED,ACU, hospital ward or at home if discharged before 6 hours)

- VAS pain score- collected by trial team (potentially using App)
- Vital signs- standard care
- Time to analgesia
- Adherence to protocol
- Resource usage questionnaire

5. Trial procedure after 6 hours and/or at disposition home/hospital bed



At discharge

- Time to readiness for discharge
- Cumulative opioid use
- Length of stay
- Patient satisfaction
- Adverse events
- Social determinants of health
- EQ 5D
- Resource usage questionnaire

Day 14 and 28 from randomization

- Patient satisfaction
- Adverse events
- Readmission
- EQ 5D patient and care-giver
- Resource usage questionnaire