

ConSEPT: Convulsive Status Epilepticus Paediatric Trial: **Challenges and Issues**



Paediatric Research in
Emergency Departments
International Collaborative

Outline of Session

- Background
- Multicentre Trials
- Low Volume Studies
- ConSEPT specific
- Process issues
- Discussion /Sharing of issues



Background.....



Basic Challenges and Issues – **Multicentre Trials**

- Time
- Staffing
- Departmental structure
- Roles
- Space
- Countries



ConSEPT – Low volume study

- Less paperwork
- Space = time and physical
- Managable
- Time spent elsewhere
- Slower to recognise issues
- Easy to put on hold
- Schedule time



ConSEPT Consent

- Retrospective
- Written consent to remain in study and for videos to be used sought at earliest possible time after emergency stabilisation has occurred.
- Obtained by senior clinician (most often Site Investigator)



Data Collection

- Paper based CRF's
- Repetitive
- Low Volume
- Relatively simple to complete



Redcap Database

- Slow to progress to date
- Currently been developed/access issues
- March – trial period/training
- April – go live





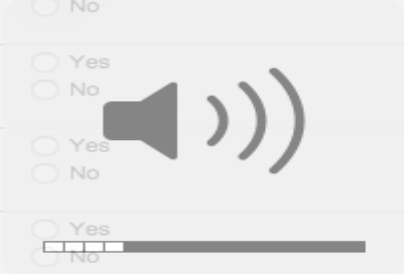
Redcap Database

Study Number <small>* must provide value</small>	<input type="text"/>
3.1 Date of Birth <small>* must provide value</small>	<input type="text"/> <small>31</small> <input type="button" value="Today"/> D-M-Y
3.2 Sex	<input type="radio"/> Male <input type="radio"/> Female reset
3.3 Patient initials	<input type="text"/>
3.4 Ethnicity <small>* must provide value</small>	<input type="radio"/> Participants enrolled in New Zealand <input type="radio"/> Participants enrolled in Australia <input type="radio"/> Participants enrolled elsewhere reset
Participants enrolled in NZ <small>* must provide value</small>	<input type="checkbox"/> New Zealand European <input type="checkbox"/> Maori <input type="checkbox"/> Samoan <input type="checkbox"/> Tongan <input type="checkbox"/> Niuean <input type="checkbox"/> Chinese <input type="checkbox"/> Indian <input type="checkbox"/> Other (such as Dutch, Japanese, Tokelauan)
Please state	<input type="text"/>
Participants enrolled in Australia <small>* must provide value</small>	<input type="checkbox"/> European <input type="checkbox"/> Aborigine/Torres Strait Islander <input type="checkbox"/> New Zealand Maori <input type="checkbox"/> Samoan <input type="checkbox"/> Tongan <input type="checkbox"/> Niuean <input type="checkbox"/> Chinese <input type="checkbox"/> Indian <input type="checkbox"/> Other (such as Dutch, Japanese, Tokelauan)
Please state	<input type="text"/>
Participants enrolled elsewhere <small>* must provide value</small>	<input type="checkbox"/> TBA <input type="checkbox"/> TBA <input type="checkbox"/> TBA
3.5 Date of ED Presentation <small>* must provide value</small>	<input type="text"/> <small>31</small> <input type="button" value="Today"/> D-M-Y
3.6 Time of ED Presentation	<input type="text"/> <input type="button" value="Now"/> H:M



Redcap Database

Record ID	<input type="text"/>	
Date enrolled <small>* must provide value</small>	<input type="text"/>  31 <input type="button" value="Today"/> D-M-Y	
Date of Birth <small>* must provide value</small>	<input type="text"/>  31 <input type="button" value="Today"/> D-M-Y	
Participants initials <small>* must provide value</small>	<input type="text"/>	
Study Number <small>* must provide value</small>	<input type="text"/>	
Q1: Inclusion Criteria Patient is aged between 3 months and 16 years <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No	reset
Q1: Inclusion Criteria Patient is currently in Convulsive Status Epilepticus (CSE) <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No	reset
Q1: Inclusion criteria Patient has had (or looks likely to have) 2 doses of benzodiazepine <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No	reset
Q2: Exclusion Criteria Patient has card indicating previous randomisation in ConSEPT study	<input type="radio"/> Yes <input type="radio"/> No	reset
Q2: Exclusion Criteria Patient has received phenytoin, levetiracetam, phenobarbitone or paraldehyde in last 24 hours	<input type="radio"/> Yes <input type="radio"/> No	reset
Q2: Exclusion Criteria Patient is on regular phenytoin or levetiracetam	<input type="radio"/> Yes <input type="radio"/> No	reset
Q2: Exclusion Criteria Patient has management plan easily available that states do not give phenytoin	<input type="radio"/> Yes <input type="radio"/> No	reset
Q2: Exclusion Criteria Patient is allergic to phenytoin or levetiracetam	<input type="radio"/> Yes <input type="radio"/> No	reset
Q2: Exclusion Criteria Patient is having Convulsive Status Epilepticus due to obvious major head injury	<input type="radio"/> Yes <input type="radio"/> No	reset
Q2: Exclusion Criteria Patient is having Convulsive Status Epilepticus due to obvious pre-eclampsia due to late pregnancy	<input type="radio"/> Yes <input type="radio"/> No	reset



Videos for Redcap

- Ability to upload videos < 1 minute
- Instructions on how to upload if > 1 minute



ConSEPT study Videos

- Key limitation of study design
 - Those assessing primary outcome remain unblinded to treatment allocation
- Blinded confirmation of primary outcome
 - In order to increase the robustness of the primary outcome assessment this will be video recorded
 - Will be independently assessed by a primary outcome assessment committee who are blinded to the first drug given



ConSEPT study - Video

- Video record the following at the time of primary outcome assessment:
 1. Randomisation envelope with Study Number
 2. The assessment of tone in limbs:
 - (i.e. flexion of bilateral ankles for clonus, or flexion of bilateral elbows)
 - ~10 second recording and verbally confirming the presence or absence of increased tone



ConSEPT study - Video

3. The assessment of jerking movements by recording the hands of the patient

- in cases of unilateral seizures – record the affected side or if predominantly lower limb seizures, the lower limbs are to be used)
- ~ 20 second recording and verbally confirming the presence or absence of jerking movements

–4. The assessment of jerking movements by recording the eyes of the patient

- (eyelids may have to be opened)
- ~10 second recording and verbally confirming the presence or absence of nystagmoid jerking eye movements



ConSEPT study - Video

- These assessments are what would be standard of care to determine the cessation of seizure activity
- Videos to be made with iPod
- Ethics approval granted



Envelope Opening

- Envelopes opened and patient stops seizure.
- Envelopes opened in error.
- Depends on situation.
- Document on envelope tracking log
- Site specific ways to deal with this



Missed Patients

- Difficult and Complex patients
- Often present out of hours
- Visibility



Visibility



Missed Patients

- Difficult and Complex patients
- Often present out of hours
- Visibility

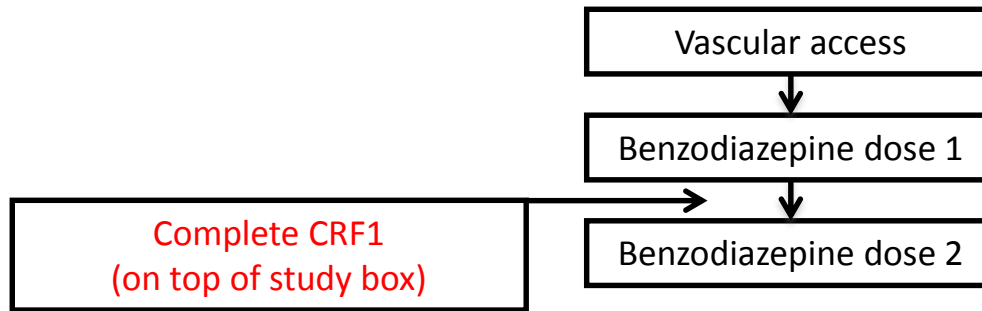
- Communication
- Availability – to team



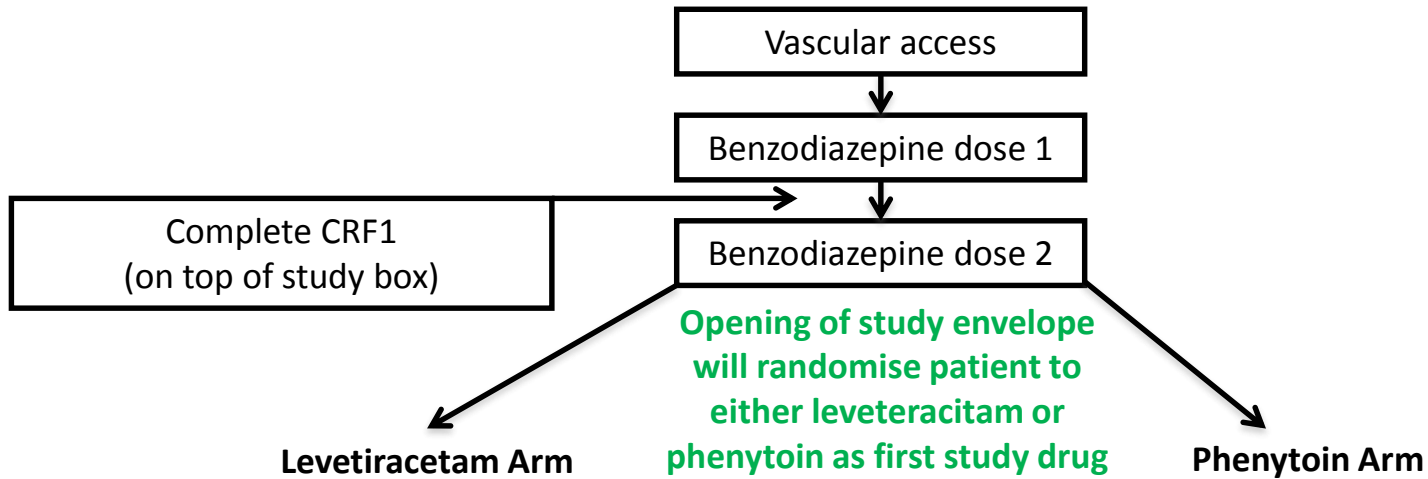
Study Process

- Low Volume – most staff will never be involved
- Keeping interest without overload
- Occurs in stressful environment
- Family
- Consent Process
- Instructions
- Appears confusing but.....

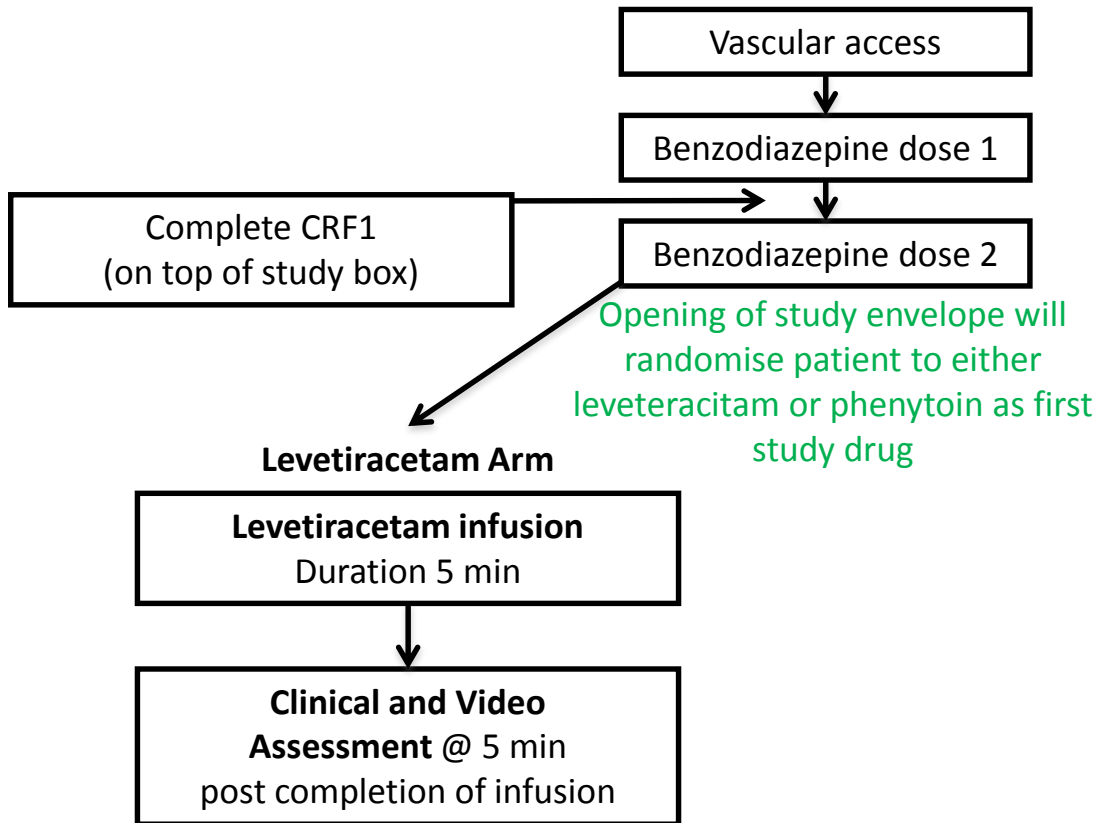
Study process



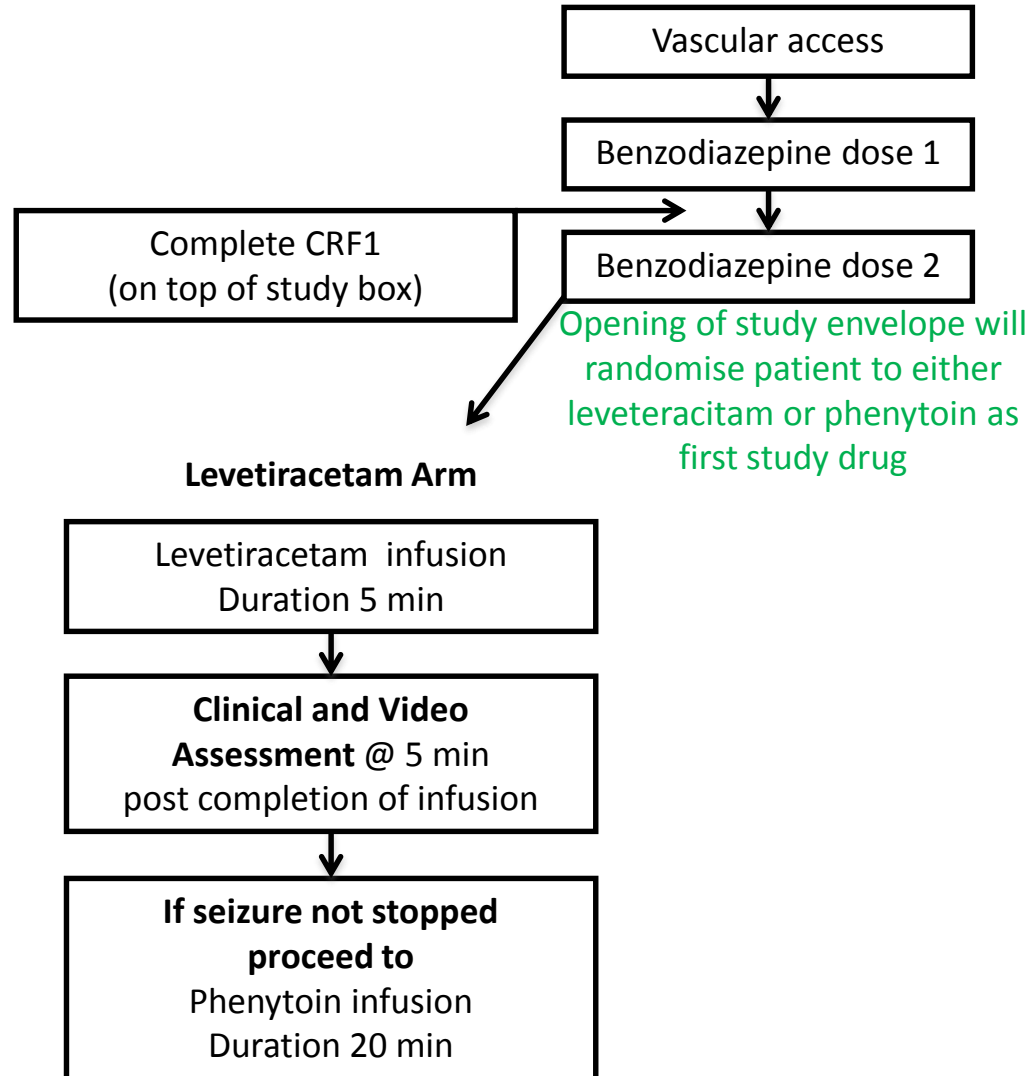
Study process



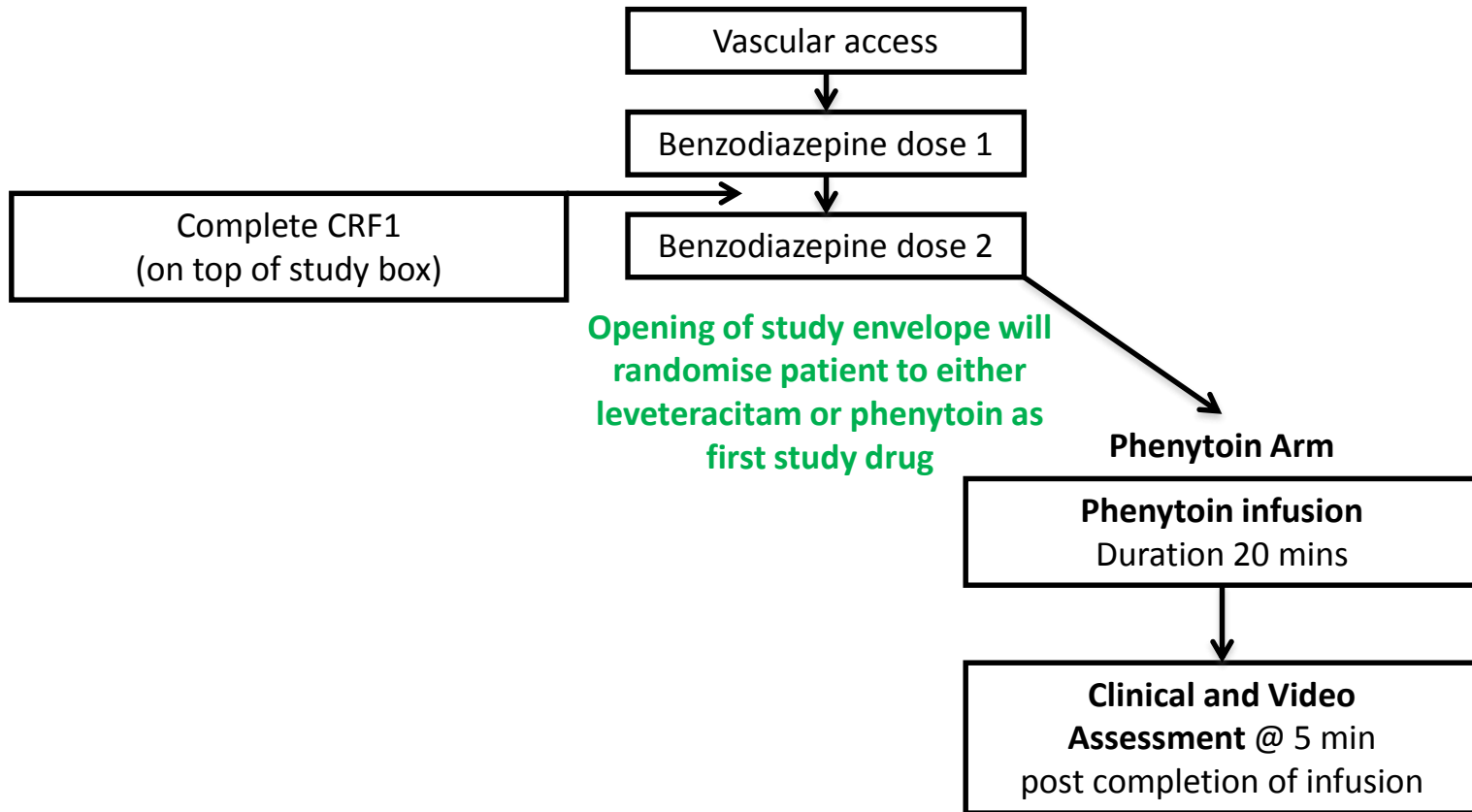
Study process



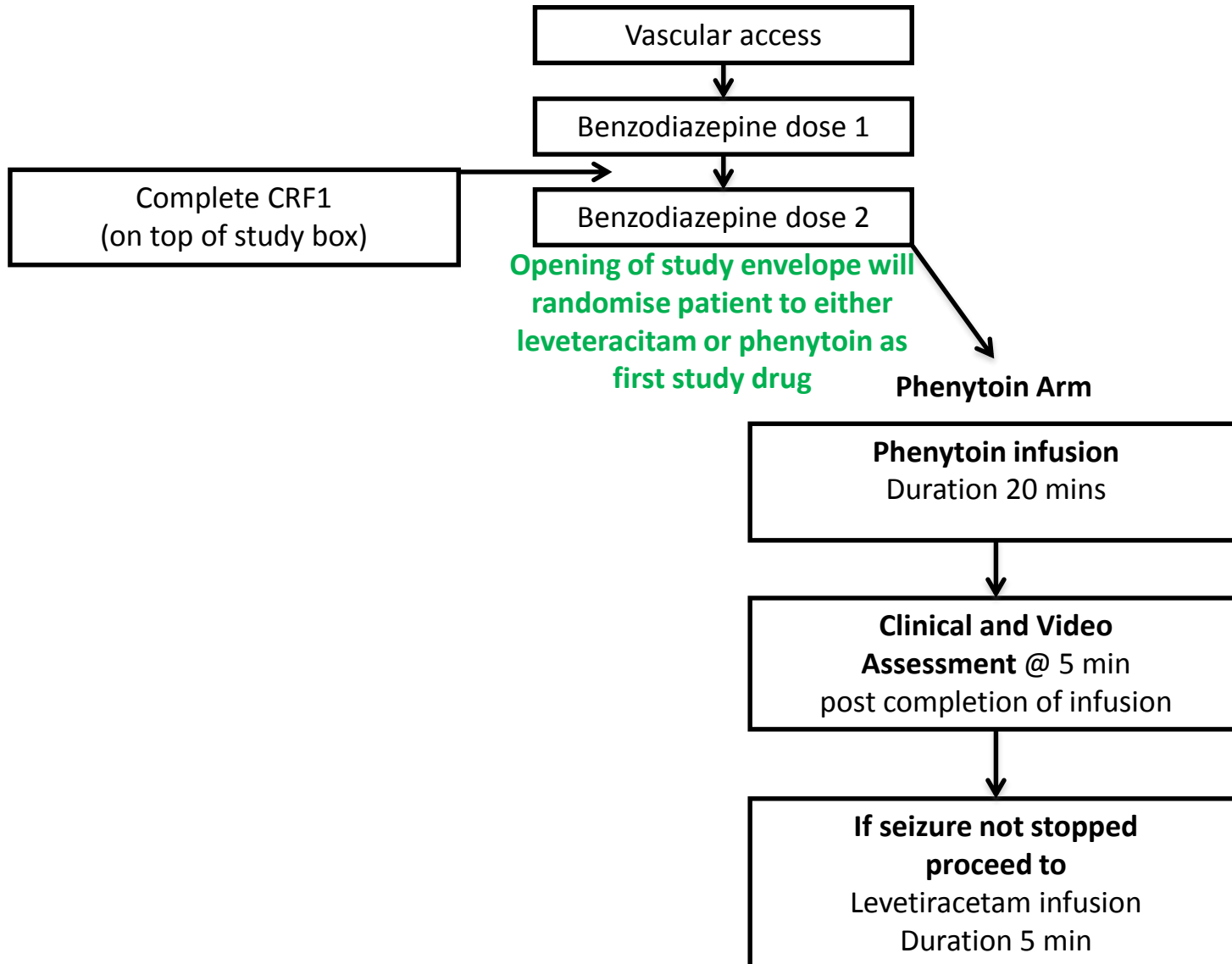
Study process



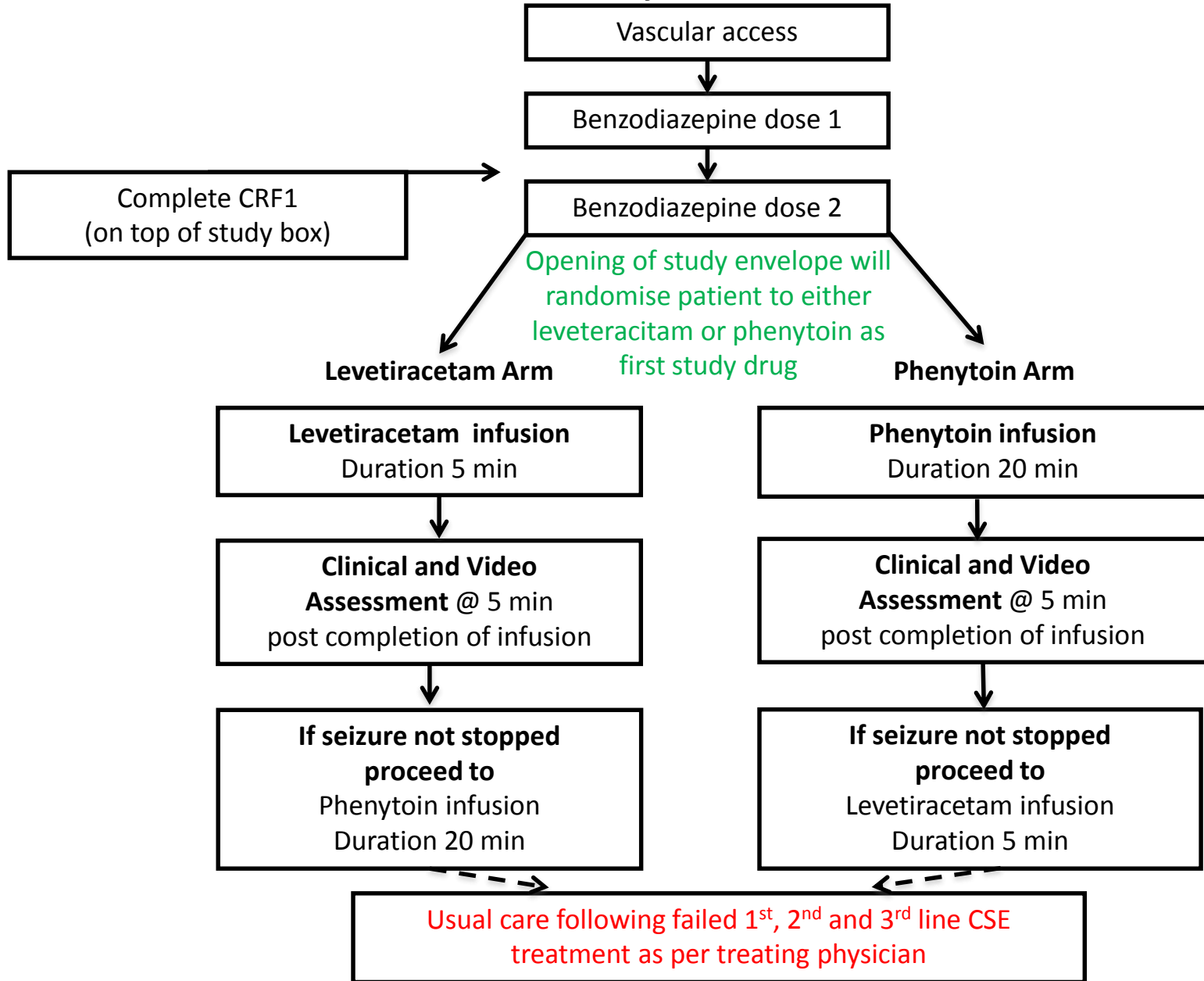
Study process



Study process



Study Process



Open discussion...

