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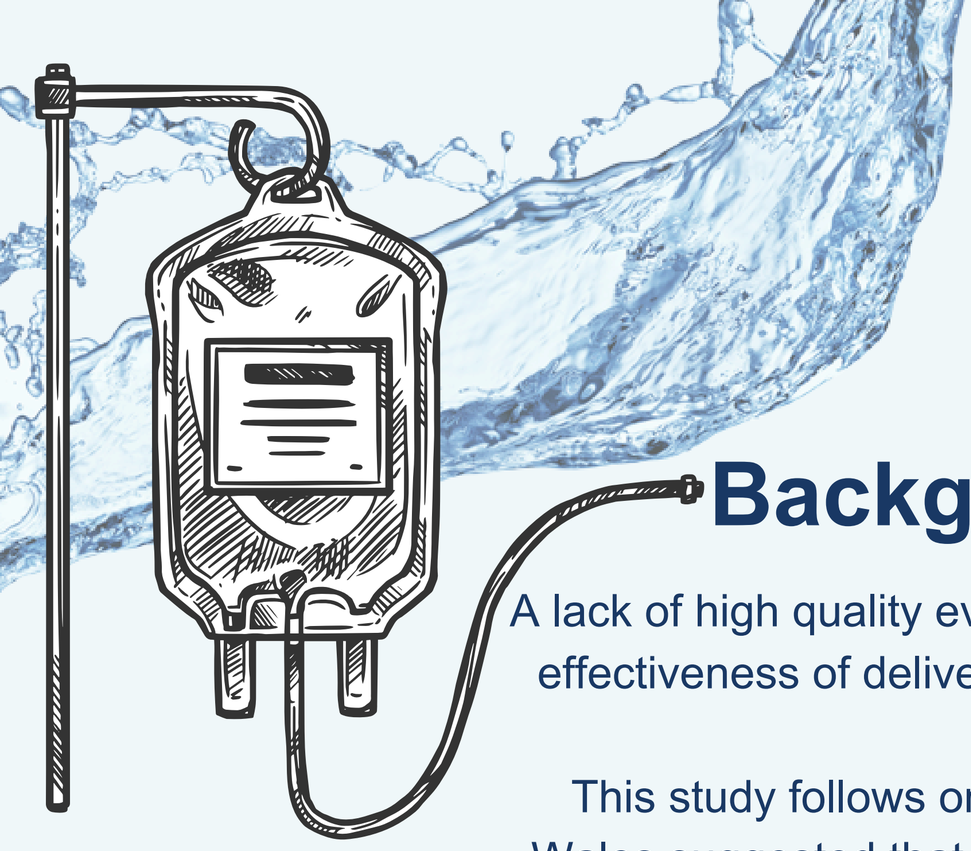
CHELsea II

Cluster randomised trial of clinically assisted hydration (CAH) in patients in the last days of life.



Background

A lack of high quality evidence means that the use of CAH is variable and we are unsure on the actual effectiveness of delivering CAH at the EOL. There is often no clear reason to indicate whether CAH should be commenced or discontinued.

This study follows on from a feasibility study conducted with 200 cancer patients in England and Wales suggested that whilst it may delay the onset of delirium it can also cause side effects in some patients (fluid retention). This larger study is being delivered to evaluate the role of CAH at EOL and to determine if the benefit outweighs the risk.

Trial summary

- The aim of the CHELsea II trial is to assess whether CAH can prevent terminal agitation (delirium)
- To explore if CAH affects other EOL problems (e.g noisy breathing, shortness of breath)
- To investigate any side effects of giving CAH and also if it has an impact on length of survival
- This evidence will assist in informing EOL care plans as these problems are distressing for patients, carer givers, loved ones and HCPs which often require the patient to be sedated in the last days of life
- The patient will be on the study for two weeks

Design & Methods

- 80 hospices/ hospitals in UK. 1,600 patients in the last weeks of life.
- The study is a cluster randomised trial, with hospices/hospitals ("clusters") randomised to one of two standard (usual) interventions.
- **Intervention A** involves supporting the patient to drink, regular mouth care, and management of pain and other symptoms.
- **Intervention B** involves supporting the patient to drink, regular mouth care, management of pain and other symptoms, and CAH. The CAH will be given either by IV or SC. The volume is based on patient's weight and the decision to continue/ discontinue the fluids will be made by the patients usual doctors/ nurses.
- Patients will be assessed for EOL problems every 4 hours and data will be collected on the presence of these problems - use of medications and any side effects. (These are logged in an observation log)

Agile teams input

We provided support at two sites (CMH Hampshire in West End and Mountbatten Isle of Wight in Newport). The hospice team undertook data collection (recruitment and filling out a observation charts). Once the participant had completed their time in the study, we transcribed the data onto the paper Case Report Form (CRF) using the observation charts and SystmOne (an electronic system).

Challenges

- Gaining access & learning new systems
- Support on the study commenced unexpectedly and despite requests to the study team we did not receive formal SI's. As a result, we had to formulate our own with brief input from a team member in another area
- Having to learn as we went along

Successes

- When the IoW site opened this meant that we had comprehensive instructions which could be used to support delivery there.
- We have completed recruitment at Mountbatten Hampshire!

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