H4RT

Newsletter 4, March 2019

Doing trials is challenging. We need to recognise when, despite widely held beliefs, actual evidence is lacking and be willing to offer randomisation to our patients. For decades we have had relatively few non-pharma trials to offer patients, so this requires a culture change. Then we need to work hard systematically to evaluate an intervention that has shown promise and in doing so, we have to avoid the temptation to start using it prematurely, before our evaluation is complete. This was the problem for EVOLVE, when nephrologists saw the PTH come down with Cinacalcet and moved patients on placebo onto active drug during the trial. The end result – a null effect.

If high-volume HDF reduces cardiovascular and infection outcomes then we need to demonstrate this once and for all so that we can justify it being offered to everyone. If being able to achieve high-volume HDF is just a surrogate for being healthier (e.g. better blood flow through your fistula) then we should be putting efforts into developing new ways to improve outcomes for our patients.

Thanks for all your efforts in recruiting people, keeping them in the trial and of course delivering high-volume HDF.

Dr Fergus Caskey
Chief Investigator of H4RT
Consultant Nephrologist North Bristol NHS Trust

Trial manager - Sunita Procter

A massive thank you to our 25 sites for recruiting 667 patients into the H4RT trial. We are in the process of training and opening a further 3 sites.

Our central research nurse training day in October 2018 was well received and at this point we clarified our definition of high-volume HDF and what was a deviation from achieving high-volume HDF in line with the H4RT study protocol. High-volume HDF was confirmed as being 21+L **adjusted to body surface area (BSA).** Since November 2018 patients allocated to high-volume HDF are **considered to have deviated** if they are **not *aiming* to achieve a substitution volume of ≥ 21litres adjusted for BSA for two consecutive months**. Thank you for completing the compliance records each month and letting us know how patients are getting on with their allocated treatment and compliance.

We are looking forward to the Investigator meeting on 1st May 2019 in Birmingham. It will be an opportunity for shared learning on delivering high volume-volume HDF and maximising recruitment at your site. Thanks for all your hard work and hope you all have a good Easter break.

Lead Research Nurse – Karen Alloway

We continue with the RN monthly teleconferences, with sites split into two groups. Dialling in to these is a useful way of connecting with staff at other sites and sharing experiences. We circulate minutes to all of the RNs in the group following these. Please do check these minutes, especially if you have been unable to dial in, as they include study updates and useful tips on improving recruitment and compliance.

The monthly news email gives you information on how your site compares with others in recruitment and a picture of recruitment for the study as a whole. We name the top recruiting sites each month, the highest receiving a small reward. It is also a forum for questions and responses to these to be shared widely as we know that similar queries and concerns are often experienced by several sites.

Qualitative Researcher – Julia Wade

QuinteT Recruitment Intervention

Thanks to those who have contributed more audio recordings – I know it can be daunting so it's been great to have some of you be so positive about the feedback you've received on these.

Keep returning updated screening logs at the end of each month, even if there hasn't been much recruitment activity as it helps us get the overview of activity across centres.

Saving time when identifying which patients are eligible and can be approached about H4RT

Draw up a list of eligible patients on a unit and arrange a meeting with the relevant consultant going through this list and establishing if the consultant is happy in principle for an approach. This can speed the process of identifying who can be approached about H4RT.

It may then be possible to approach as many as possible on one shift. If the consultant has a regular presence on the unit you can try to approach the patient when the consultant is there to support the process: patients are more likely to agree to take part if their consultant has reassured them that they see no reason for them not to be involved in the study.

Trial Administrator – Nicola Giles

As always, thank-you for taking the time to send me your data as well as the responses to data queries. If you have any queries that you are unsure how to resolve, please do get in touch.

Key Contacts:	
Chief Investigator	Dr Fergus Caskey Email: Fergus.Caskey@bristol.ac.uk
Trial Manager	Dr Sunita Procter Telephone: 0117 928 7286 Email: Sunita.Procter@bristol.ac.uk
Lead Research Nurse	Mrs Karen Alloway Telephone: 0117 414 8110 Email: Karen.Alloway@nbt.nhs.uk
Qualitative Researcher (QRI)	Dr Julia Wade Telephone: 0117 928 7362 Mobile: 07847 618455 Email: julia.wade@bristol.ac.uk
Project Administrator	Mrs Nicola Giles Telephone: 0117 331 3913 Email: Nicola.Giles@bristol.ac.uk Email: h4rt-study@bristol.ac.uk

Documents and information are available on our website https://www.bristol.ac.uk/population-health-sciences/projects/h4rt-trial

And as always, please feel free to contact us if you have any queries, we are here to help.

Follow us on Twitter: @H4RT_UK

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