



Seasons Greetings from the HERO Study

Season's Greetings

Frochliches Weihnachten

Joyeux Noel

Buon Natale

Feliz Navidad



To our hardworking site study staff:

*the Trial Management Committee
and all of us here at the AKTN
wish you a safe and happy holiday.*

Message from David Johnson



Welcome to the first edition of the HERO newsletter.

I am the Principal Investigator for the HERO trial and have been a practicing nephrologist for 14 years. I hold a number of key administrative and research positions at the Princess Alexandra Hospital and the University of Queensland.

This newsletter will serve to update Investigators and Site Coordinators about trial status/progress and any new information relating to the trial.

Thank you very much for your continued support of the HERO trial, and I wish you and your families a safe and happy holiday.

I look forward to a successful collaboration with you all.

David

Approximately 25% of all patients screened are ineligible for the HERO trial because of the presence of absolute or functional iron deficiency indicated by TSAT of less than 20%.

See page 4



Inside this issue:

Site Status	2
New Project Officer	2
Electric Screening Logs	2
FAQ	3
Screening Tests—Using Previous Test Results	3
HERO Humour	3
Patient Recruitment	4
Changes to Study Protocol	4
How Well Do You Know Your HERO?	4

HERO Site Status

Since the HERO trial initiation meeting held in November 2008, the trial has made steady progress, despite a few delays involving staff turnovers and study medication availability.

The HERO trial now has 6 sites actively recruiting and 2 of these have enrolled at least one patient. The total number of patients enrolled is 6, and a further 7 sites are expected to begin screening in the New Year.

With a target of 110 patients this trial is now well on its way to a successful 2010.



I don't care what day it is.
Four hours is four hours.

New Project Officer



Hello to all HEROs! My name is Donna and I am the new Project Officer for the HERO trial. Some of you may know me through my former role as the AKTN Centre Support Officer. I am looking forward to working with you all over the coming year.

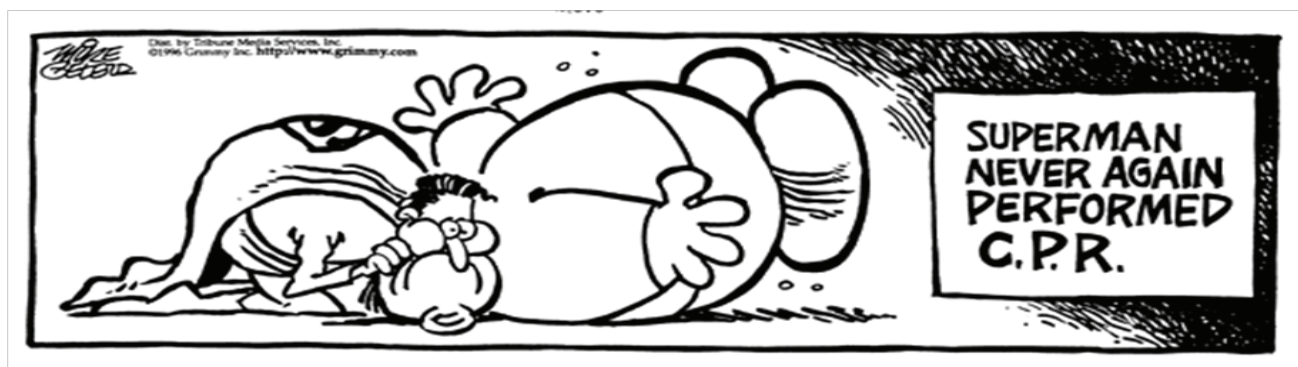
Congratulations to Alicia, who is now able to take up her new position as Project Manager, overseeing all of the Network's trials, and providing valuable support to us all.

All the best for the New Year

Donna Reidlinger 07 3240 5961

Electronic Screening Logs

Just a reminder to sites to please use the excel spreadsheets supplied by the AKTN to log patient screening details. De-identified copies will be requested approximately monthly to enable us to monitor recruitment and screening. The Screening Logs will also help us to identify inclusion/exclusion criteria that present the biggest barriers to patient recruitment. Please contact me on 07 3240 5961, or send me an email at d.reidlinger@uq.edu.au if you require another





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Frequently Asked Questions

Q: If a potential trial participant is on Home Haemodialysis and will not agree to visit the clinic for monthly visits is it acceptable for the patient to take their own blood as usual, and bring this to the clinic as part of their normal care?

A: Obviously this patient would not be able to participate in the HERO sub-studies, however she or he would still be eligible for the main study. It is acceptable for the blood drawn date to differ by a couple of days to the patients physical examination.

Q: Is a patient who is not B12 deficient but receiving regular B12 injections eligible for the HERO study?

A: Yes, this patient would be eligible to participate in all aspects of the study.

Q: I have a patient who is not on a set EPO dose. Am I able to average out her dose to assess eligibility or does she have to be on the dosage as set by the study protocol (≥ 200 IU/kg/week) every week in order to be considered? ?

A: Yes, averaging the dose to assess eligibility is fine.

Screening Tests—Using Previous Test Results

Results for the following tests obtained **up to 4 weeks** prior to the screening visit may be used to assess a patient's eligibility:

- Vitamin B12 or folate
- PTH Level
- Serum aluminium
- Iron Studies*

* Please note that if previous results for the Iron Studies have been used at the screening visit, the patient will need to have their Iron Studies retested at baseline. Conversely If new results are obtained at the screening visit then these results can be re used at baseline (ie the tests do not need to be redone at baseline).

Results obtained **up to 12 weeks** prior to the screening visit can be used for:

- Urea reduction/single pool Kt/V (HD) or weekly Kt/V (PD)



HERO Humour

A guy sits at a bar in a skyscraper restaurant high above the city. He slams a shot of tequila, goes over to the window and jumps out. The guy sitting next to him can't believe what he just saw. He's more surprised when, 10 minutes later, the same guy walks back into the bar and sits down next to him.

The astonished onlooker asks, "How did you do that? I just saw you jump out the window, and we're hundreds of feet above the ground!"

The jumper responds by slurring, "Well, I don't get it either. I slam a shot of tequila, and when I jump out the window, the tequila makes me slow down right before I

hit the ground. Watch." He takes a shot, goes to the window and jumps out. The other guy runs to the window and watches as the guy falls to just above the sidewalk, slows down and lands softly on his feet. A few minutes later, the jumper walks back into the bar.

The other guy has to try it, too, so he orders a shot of tequila. He slams it and jumps out the window. As he reaches the bottom, he doesn't slow down at all. SPLAT!

The first guy orders another shot of tequila. The bartender shakes his head. "You're really an a**hole when you're drunk, Superman."

Patient Recruitment

An analysis of site screening logs shows that while most sites are regularly screening patients many have been unsuitable for randomisation. The top five impediments to patient recruitment identified to date are shown in table 1.

While this may be disappointing the good news is that patients excluded from the study because of these criteria can usually be rescreened after 8 weeks. Rescreening can occur a maximum of three times. Good Luck!

Table 1	
Top 5 Impediments to Patient Recruitment—HERO	
Absolute or functional iron deficiency	25%
EPO/DPO dosage not stable for ≥ 8 wks	21%
Hb not consistently low enough	14%
Recent infection or surgery	13%
Active haemolysis	7%



Meet Mr. Bates, our perfect patient. He controls his fluid levels by not drinking and his potassium, cholesterol and phosphates by not eating.

Changes to the Study Protocol

As with any trial, the protocol is an evolving document that must occasionally be altered or updated in response to feedback from regulatory authorities, the Trial Management Committee, or from the Trial Sites themselves. While we try to make these protocol amendments as infrequent as possible, especially once recruitment has commenced, they are an unavoidable part of clinical trials. There are minor changes to be made to the HERO protocol in the New Year. We will keep you all advised.

How well do you know your HERO?

Test your knowledge of the HERO trial. Answers are below

Randomisation should occur at least 3 working days prior to the Baseline visit to ensure adequate time to courier the medication to the site.

True

False

At the screening visit iron studies results obtained recently can be used for screening. How many weeks before the screening visit can the studies have been performed.

8 weeks

4 weeks

12 weeks

According to Good Clinical Practice Guidelines a Serious Adverse Event (SAE) must be notified to the AKTN (the Sponsor) within 24 hours. Which of the following is **NOT** an SAE.

Hospitalisation

Congenital Anomaly/Birth Defect

Visit to an Emergency Outpatient Facility

Death

True, 4 Weeks, Visit to an Emergency Outpatient Facility



The
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