Study Protocol Amendments

Randomized controlled trial of foam sclerotherapy for venous leg ulcers

Trial registration:
ISRCTN18090073
https://doi.org/10.1186/ISRCTN18090073

Interim statistical analysis:
An interim analysis will be conducted at 50% of the target sample size when 65 participants have completed follow-up. This will allow for a review of efficacy and futility and a further opportunity for the assessment of safety.

Failure of conservative treatment:
For participants in Group B – randomized to conservative treatment – if after six months their ulcer fails to heal, this will be considered a failure of conservative treatment. The participant and their clinical team can then consider treatment with ultrasound-guided foam sclerotherapy according to the Group A arm of the protocol. This will be considered treatment failure will be considered as such in the final analysis.

Change of address of a participating center:
Please change the address of the following participating center:
Ahmed Khairy
From: Zagazig 44519 Egypt
To: Banha 13511 Egypt