

RECRUITMENT CHALLENGES IN MRI STUDIES OF ACUTE INTRACEREBRAL HAEMORRHAGE: EXPERIENCE FROM THE TICH-2 MRI SUBSTUDY

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BACKGROUND AND AIMS

Magnetic Resonance Imaging (MRI) is widely used in clinical practice and in trials for ischaemic stroke; however, relatively few large multicentre trials for intracerebral haemorrhage have used MRI. We describe the main recruitment challenges faced in the TICH-2 MRI substudy, which is nested within TICH-2, a multi-centre randomised placebo-controlled trial of tranexamic acid in intracerebral haemorrhage (ISRCTN93732214).

METHOD

TICH-2 participants at recruiting centres were eligible for the substudy. Centres were asked to record, if applicable, the reason for non-recruitment. The recruitment window was day 2 to day 14 post-randomisation.

RESULTS

Figure 1 shows the distribution of reasons for non-recruitment (N=169). Clinical instability was the main reason for non-recruitment, accounting for 34.3% of the cases. The mean NIHSS scores (as per TICH-2 protocol) for unrecruited patients classified as clinically unstable were 19 (range 5-32, N=57), 21 (range 0-40, N=51) and 20 (range 1-38, N=37) for baseline, day 2 and day 7 post-randomisation, respectively. In contrast, for recruited patients (N=142) the mean scores were 10 (range 0-28, N=141), 8 (range 0-26, N=139) and 8 (range 0-31, N=132). Other important factors for non-recruitment include difficulty obtaining consent, patient refusal, claustrophobia and transfer to other hospitals.

CONCLUSION

Clinical instability in intracerebral haemorrhage poses a challenge for recruitment into MRI studies. This, and other factors, should be taken into consideration when designing clinical trials of intracerebral haemorrhage involving MRI.



Figure 1: Distribution of reasons for non-recruitment.