BACKGROUND

The IONA study is collecting blood, urine and oral fluid samples from people presenting to UK hospitals with severe toxicity suspected to be related to use of novel psychoactive substances (sometimes previously called ‘legal highs’) or non-pharmaceutical opioids. The latter, including heroin, are included so that the involvement of unlicensed fentanyl analogues in episodes of severe toxicity can be monitored. Sample analysis is being performed to identify the substances involved and to link these with clinical features of toxicity experienced by the participant. The study currently involves 27 study sites in England and Wales and 2 sites in Scotland. Because the study can involve adults with incapacity, separate ethical approval was required in England and Wales (15/NE/0023) and Scotland (15/SS/047).

AMENDMENT REQUESTED

This is a request for a substantial study amendment to adjust the recruitment target for England and Wales and for a small extension to the end date.

The current ethical approval is for recruitment of a grand total of 750 participants, 570 recruited in England and Wales and 180 recruited in Scotland, by 31st March 2020. Research sites in England and Wales have achieved their overall recruitment target of 570 with 6 months of the currently funded recruitment period still remaining. We would to increase their overall recruitment target by 100 (to 670) to allow them to continue recruitment until 31st March 2020. We would also like to extend the end date for the study for a further 6 months to 30th September 2020, to provide sufficient time to complete laboratory analysis of all samples collected by 31st March 2020.

The current NIHR funding of the IONA study will not continue beyond the end of March 2020, but work is being done to secure further funding from another source to allow the study to continue beyond that date, although this is not yet guaranteed. Were this funding to be secured, a further substantial protocol amendment will be requested to cover the new arrangements. The proposed additional recruitment in England and Wales to the end of March 2020 requested here would provide continuous data collection over 5 years from March 2015 to March 2020. This is important for monitoring time trends in misuse of drugs and other substances, which would otherwise be undermined by a gap in data collection between October 2019 and March 2020. In the event that further external funding is not obtained, local funds are available to cover analytical costs related to these 100 additional participants.

IONA is an observational study and there are no specific statistical comparisons planned. We are requesting additional recruitment numbers to allow further monitoring of the substances involved in severe episodes of toxicity associated with exposure to new psychoactive substances, rather than for any specific statistical comparison.

These revised recruitment targets are reflected in the updated schedule of events (Protocol V6, 21st October 2019, pages 33-34 of the clean version).