

Trial title	The effect of pamidronate treatment on bone health in patients with neuromuscular disease undergoing hip surgery
R&D PIN	R00354
EudraCT reference	2009-013777-17
REC Reference	09/H1008/105
Sponsor	Manchester University NHS Foundation Trust
Chief Investigator	Mr Michalis Zenios

The above referenced double-blind, randomised, placebo-controlled, phase II Clinical Trial of an Investigational Medicinal Product (CTIMP) was conducted at Central Manchester and Manchester Children's Hospital NHS Trust (now known as Manchester University NHS Foundation Trust) from 13/08/2010 to 05/03/2012. The purpose of the trial was to assess whether pamidronate had an effect on post-operative change in bone mineral content (BMC), bone mineral density (BMD) and bone geometry of the tibia, femur and spine in two randomised groups of children undergoing hip surgery and post-operative immobilisation in a hip spica. The treatment group received three doses of intravenous pamidronate two weeks prior to surgery. The control group received corresponding doses of saline in a fully blinded fashion.

The primary outcome measure for the trial was the Bone Mineral Content (BMC) and Bone Mineral Density (BMD) three months following surgery. Only one participant was recruited to the trial and no SAEs were recorded or notified to the Sponsor.

The recruitment target for the trial was 12 participants and involvement for each participant was expected to last for three and a half months.

The Chief Investigator of the trial informed the Sponsor Office that he was leaving the trust at the end of April 2012 and an alternative Chief Investigator could not be found. The trial had only recruited and dosed one participant and there had been difficulties with recruitment. As a result, the Sponsor decided to prematurely terminate the trial on 05/03/2012.

No participants were still receiving treatment at the time of premature trial termination. It was deemed unlikely that the data from one participant would inform the primary and secondary outcome measures.

Name: Dr Michalis Zenios

Date: 06/12/19

Signature: _____

