Full Title

A study to assess the equivalence in efficacy of anaesthesia using topical Proxymetacaine 0.5% drops versus sub-conjunctival Lignocaine 2% (without adrenaline) for subsequent Intravitreal Injections of Ranibizumab (Lucentis): A Randomized Clinical Trial

General summary

Wet macular degeneration is a disease of the elderly population causing vision loss. In arresting the progression of the disease, a drug called lucentis has shown promise and a third of patients show a significant improvement in sight. The drug is injected into the eye after the eye is made numb by putting anaesthetic drops onto the white of the eye, which most of the time is adequate. Some surgeons inject a small amount of an anaesthetic under the white of the eye in addition to using the anaesthetic eye drops. There are no recommendations for the anaesthesia method to be used for intravitreal drug administration. This was a randomised controlled trial comparing the two methods when injecting lucentis into the eye.

Publication of clinical trial results

The results of this trial have not been published. An MHRA inspection identified a critical data issue related to IMP administration and the 'masking' of the trial. The masking number and the data entry in the hospital file could not be matched and verified. These findings invalidate the data produced by the trial and the paper produced was subsequently withdrawn by the Chief Investigator.

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