CRACK IT RETINAS – Questions and Answers

Q: What is the current procedure for finding the right spot in the eye for intravitreal injection?

A: There are visual clues but it's really down to training and experience to angle the needle precisely to hit the 1mm zone required. This is the problem – not so much the failure to do the injection correctly but the length of time required to train someone to do it well.

Q: Is the needle standard?

A: A standard 0.5ml plastic syringe is used. Needle length is standard but the device may need to accommodate different needle gauges.

Q: Should the device be single-use or multi-use?

A: Both should be available for flexibility in different environments. Multi-use would be most valuable for labs where a great number of injections are done. A multi-use device would need to be sterilisable. Single-use is also handy but even more so if the device could be used sequentially on a few animals on the same day before discarding.

Q: Why does a device for human use exist if it is so much easier to inject into human eyes?

A: Some surgeons do as many as 70-80 patients a day. It's for ease rather than accuracy.

Q: How many single-use devices would you require?

A: Currently about 250 per annum. However, the market is larger than one company.

Q: If use of a device requires pressure on the eye to immobilise it, will this deform the eye and change the angle of injection?

A: We do not expect the pressure needed to fixate the eye to deform the eye itself significantly. In the clinic eyes are fixated for a variety of procedures (e.g. intravitreal injection, laser treatment) without this causing the eyeball to be deformed.

Q: Can the injection be made at various locations in the eye?

A: Yes, the 3 and 9 o'clock positions are most accessible, but around 7 o'clock is also possible.

Q: Are there strain-dependent differences in rabbit eyes that would require different devices?

A: In the two strains used most frequently in the UK, they are very similar. However, the pigmented strain used in the UK differs from that used in the US. The size of the eye and the eye socket may vary between strains.

Q: How long would it take to test a prototype?

A: Histology would be the longest part but we predict i could all be done relatively quickly. We would first test the prototype on euthanased rabbits that have been used on another study so this would depend on their availability. This would not delay the project by more than two to three weeks.

For the final prototype we plan to run a comparative study for a minimum of two weeks (as sometimes the side effects of a scratched lens only become apparent after this time). Including one week acclimatisation time and interpretation of data this is likely to be three to four weeks in total.

Q: What happens to the animal?

A: The rabbit is under general anaesthesia with local anaesthesia to the eye. It comes round very quickly after the procedure which only takes one minute. Blood samples are then taken for PK measurements.

Q: Is there any benefit in a device that can be used single-handedly?

A: No, but it must be useable by left and right-handed people.

Q: What is the volume of injection?

A: 50ul in the UK, up to 100ul in the US.

Q: The brief refers to publication of findings. What was intended?

A: Publication of the utility of the device for dissemination purposes and also in peer reviewed laboratory animal journals.

Q: Is eye ellipticity marked enough to use to orient the device?

A: It is a possibility.

Q: Is needle safety an issue?

A: No more than usual – the needle would be disposed of in the sharps bin, or the whole device if single-use.

Q: Have IP searches been done to check on relevant technology and freedom to operate?

A: No.

Contact the NC3Rs if you have further questions about this challenge and we can facilitate communication with the Sponsor.

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