Northern Health and Social Care Trust

Research & Development Project End of Study Report Pro-forma

Please complete this proforma when your study has ended and return with a copy of the full report of your study to Margaret Smyth, Research Governance Manager, NHSCT R&D Office, Governance Dept., Bush House, Bush Road, Antrim BT41 2QB

1. **Full Title of Project: NRP10- 0180/03 A Qualitative study comparing two different treatments for local anaesthesia of lacerations**
2.

2. **Details of Chief Investigator**:

Surname: Jenkins **Title: Dr**

First Name: Mark

Address: Accident & Emergency Department
Antrim Area Hospital
45 Bush Road
Antrim
Bt41 2RL

Telephone No: 02894424259

E-mail: Mark.Jenkins@northerntrust.nhsct.net

3. **Timetable**

3(a). Start date: 1/1/10 **3(b). Completion date 31/1/11**

4. **Main research question or hypothesis**.

The aim of this study was to evaluate a topical anaesthetic putty versus injected lidocaine, developed to regulatory standards, in the repair of lacerations

5. **Summary of main findings (can be completed on additional sheet)**

The putty had to be made to GMP and to MHRA standards prior to the clinical trial. To develop it to GMP quality, a number of *in vitro* experiments had to be developed to ensure loading of the putty could be developed. Such putty loading also had to show that the release of the drugs was possible and also measurable. In doing such studies the stability of the drug loaded putty had to be demonstrated.

To achieve MHRA approval not only was the evidence required to show stability, but also low levels of bio-burden and effectiveness of sterilisation had to be shown. The group was able to demonstrate this. This data was sufficient to satisfy the MHRA, enabling permission to be granted enabling commencement of a phase 2 clinical

The MHRA licence preceded the REC decision to allow a clinical trial. The methodology comprised the recruitment of 110 patients in a randomised controlled trial, using a non-inferiority design. The result, which was powered to show a difference in analgesia, showed no difference in the two groups. There were no differences in the infection or dehiscence rate of the wounds

6. Details of completed publications or conference presentation from this project (please provide full details of any publications, journal articles, and conference presentations).

1. Evaluation of wound residence properties of non-drug-loaded PVA-borax hydrogels. Little C, Kelly O, Jenkins MG, Murphy DJ, McCarron P. Wounds-UK Harrogate UK November 2008.
2. Evaluation of wound residence properties and physical properties of non-drug-loaded pva-borax hydrogels in lacerations. Symposium Advanced Wound Care Dallas 2009
3. Evaluation of wound residence properties and physical properties of non-drug-loaded poly-(vinyl alcohol)-borax hydrogels in lacerations. European Wound Management Association Helsinki 2009
4. A non-inferiority study of the clinical effectiveness of anaesthesia obtained via application of a novel topical anaesthetic putty compared to infiltration of lidocaine for the treatment of lacerations in the Emergency Department. Mark G Jenkins Carol Little, Julie McDonald, Paul McCarron. College Emergency Medicine Birmingham 2010
5. A non-inferiority randomised controlled study comparing anaesthesia obtained via application of topical lidocaine putty compared to infiltration of lidocaine for the treatment of acute lacerations in the emergency department. Jenkins MG, McCarron P, Little C, McDonald J. European Wound Management Association Brussels 2011
6. The use of topical anaesthesia during repair of minor lacerations in Departments of Emergency Medicine: a literature review.Little C, Kelly OJ, Jenkins MG, Murphy D, McCarron P. Int Emerg Nurs. 2009 Apr;17(2):99-107. Epub 2008 Dec 27. Review.
7. A non-inferiority study of the clinical effectiveness of anaesthesia obtained via application of a novel topical anaesthetic putty compared to infiltration of Lidocaine for the treatment of lacerations in the emergency department. Jenkins MG, McCarron P, Little C, McDonald J. Emergency Medicine Journal;27:A1-A2 http://emj.bmj.com/content/27/Suppl_1/A1.4.abstract

7. Plans for dissemination (please describe your plans for future dissemination of this work for maximum patient benefit , including detains of dissemination to participants, academic community, NHS practitioners and others)

Mark Jenkins and Paul McCarron continue to work on the development of this novel putty material. Both have initiated an extensive programme of development, which is looking at incorporating a range of therapeutic agents into the putty. The most obvious plan is to adapt the putty so that it can be used to treat chronic ulceration. Given the prevalence of this condition and the burden it imposes on the NHS, there is considerable scope to have an impact on treatment by using our putty. Indeed, we would anticipate that in the near future we will seek funding for this work, possible through the PHA.

8. **Impact of your project –**

What is/or will the impact of your project on the following:

a. **Individual patient management:-**

We have shown that it is possible to produce and deliver drugs via a PVA borax putty. If this is allowed to go into production it will lead to another treatment strand for wound care.

b. **Service Delivery:-**

c. **Changes in patient outcomes**

9.

Signature: 

(Chief Investigator's Signature)

Signature: _____

(Site Principal Investigator's Signature)

Date: 8/11/12