## Study Process - Steps for ED doctors

**1. Identify eligible patient (aged 18-65 yrs, within 48 hrs of whiplash injury, pain score ≥5 / 10, non-pregnant, non-breastfeeding)**

**2. Contact research team:**

**Dr Scott Farrell 0400 550 548 or Dr Jane Nikles 0408 599 033, or** **Dr Gerben Keijzers 0415 735 166, or Prof Michele Sterling 0488 196 862**

**Based on their advice/time of day etc 🡪 either**

**- i) Screen and consent the patient,**

***OR***

- **ii) Complete permission to contact form so UQ researchers can follow up with the patient**

## More detail on these two options:

## i. Screen and consent the patient yourself

The documents required for screening and enrolling a patient, as well as the medication, can be found in the study kit bags in the ED drug room (near Minors at GCUH).

###### 1. Pre-screening

Check that there are no medical conditions or medications that would exclude the patient (refer to Study Information Leaflet for Doctors), including pregnancy and breastfeeding in women, and depression.

###### 2. Obtain Informed Consent

Explain the trial to the patient, explain the risks and benefits, answer any questions, ask them to sign the consent form, and then countersign the consent form yourself. Keep this in the clipboard in the study drawer in the drug room (and make a copy to give to the patient for their reference).

**For further information about obtaining informed consent, see**

<https://www.goldcoast.health.qld.gov.au/sites/default/files/Collecting%20Consent.pdf>

###### 3. Screening

Fill in Screening Form (Form A) and keep this in the clipboard in the study drawer in the drug room.

Eligible women of child bearing age will need to undergo a pregnancy test (blood test) and will not be able to proceed to the trial unless this is negative. Patients who score 3 or more on the Patient Health Care-2 (2-question screening questionnaire for depression located in the screening form), will not be eligible for the trial.

See addendum in protocol for further care for these patients.

###### 4. Write the script

Pregabalin/placebo 75 mg 1 capsule bd for 5 weeks using the usual QH script. Give the script to the treating nurse who will obtain a study medication and paperwork kit from the ED drug room.

The nurse or doctor needs to:

1. go through the medication instructions (dosing guidelines - found in the kit) and possible side effects with the patient (see Pregabalin prescribing information)
2. give patient the bag containing all the study materials.

The patient will then continue with usual care for whiplash injury.

*5. Give patient bag containing medication and paperwork*

Give the patient the bag with the medication kit (pregabalin/placebo), sheet dosage schedule (AM or PM start – remove the one which is not applicable), participant information sheet, baseline questionnaire (Form B), symptom diary, whiplash information booklet, return envelope and safety card (all in medication kit bag).

*6. Put completed paperwork into clipboard in clipboard in the study drawer in the drug room*

Complete the drug accountability log (on clipboard), and put the log, script, Form A and consent form back into the trial medicine drawer (VERY IMPORTANT).

*7. Tell patient the research team will call them within 72 hrs*

*8. Notify research team*

Provide the patient’s contact details to someone in the trial research team so we can follow the patient up over the 5 weeks of the trial.

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***OR***

## ii. Complete Permission to Contact form

*1. Briefly explain trial and explain that the UQ research team can contact the patient to provide further detail*

*2. Ask patient to sign Permission to Contact form located in the study drawer in ED drug room (near Minors at GCUH), Resus, Acute & SSU*

*3. Return Permission to Contact form to the folder*

*4. Notify research team*

Provide the patient’s contact details to someone in the trial research team so we can follow the patient up and discuss the trial with them.

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### Investigators

The study brings together a team of researchers from The University of Queensland and the Gold Coast University Hospital:

[**Professor Michele Sterling**](https://www.griffith.edu.au/professional-page/michele-sterling)**,** [**Dr Gerben Keijzers**](https://www.griffith.edu.au/health/school-medicine/research/research-active-academic-title-holders/dr-gerben-keijzers)**,** [**Dr Jane Nikles**](http://researchers.uq.edu.au/researcher/555)**,** [**Dr Scott Farrel**l](https://app.secure.griffith.edu.au/phonebook/phone-details.php?id=1680693&string=scott+farr)**, and Prof Geoff Mitchell.**

[**Professor Michele Sterling**](https://www.griffith.edu.au/professional-page/michele-sterling), Director of the NHMRC Centre of Research Excellence in Recovery Following Road Traffic Injuries, Recover Injury Research Centre, The University of Queensland.  Professor Sterling is a member of the Australian College of Physiotherapists. She is internationally recognized for her expertise in the physiological and psychological processes underlying chronic pain and disability following Road Traffic Crash injury and the assessment and treatment of such injuries. Her main focuses of research are: the physiological and psychological factors underlying musculoskeletal pain and injury; the prediction of outcome following whiplash injury and the clinical translation of research findings to clinical practice.

[**Dr Gerben Keijzers**](https://www.griffith.edu.au/health/school-medicine/research/research-active-academic-title-holders/dr-gerben-keijzers),

Gerben Keijzers is a Senior Staff Specialist at the Gold Coast University Hospital Emergency Department (Queensland, Australia) and has an honorary Professor of Emergency Medicine position with Bond University and an Associate Professor position with Griffith University.

Gerben Keijzers completed a Master's degree in Epidemiology and medical degree in Nijmegen, The Netherlands. He came to Australia in 2002 and completed his Fellowship in Emergency Medicine in 2008. He has a PhD in quality of trauma care. He works clinically, conducts clinical research and is a clinical supervisor for medical students on Emergency Medicine rotation.

His focus is on encouraging collaborative clinical research and is the principle or site investigator for several national and state funded studies. He has over 65 peer-reviewed publications and over 3 Million AUD in successful competitive grant applications.

He is the immediate past chair of the Queensland Emergency Research Collaborative, a member of the clinical trials group of the Australasian College for Emergency Medicine, a member of the research advisory committee for the Emergency Care institute and is section editor for the peer reviewed journal Emergency Medicine Australasia.

**Associate Professor Jane Nikles** is a registered medical practitioner who has conducted clinical trial research and general practitioner (GP) research at UQ for over 20 years. She has a growing reputation in research on whiplash and other musculoskeletal pain after road traffic crashes and has published two papers and obtained 4 grants in this area. She also brings substantial experience in conducting clinical trials, several of which have been conducted in GP. She has organised EBM workshops for GPs and analysed data on GP management of whiplash.

[**Dr Scott Farrell**](https://app.secure.griffith.edu.au/phonebook/phone-details.php?id=1680693&string=scott+farr) is a Postdoctoral Research Fellow with Recover Injury Research Centre at The University of Queensland.  His research investigates peripheral musculoskeletal and neurological contributors to chronic neck pain, with a particular focus on whiplash associated disorder. He has a clinical background as a physiotherapist and postgraduate training in anatomical dissection, immunohistochemistry and magnetic resonance imaging. Dr Farrell has taught into medical, physiotherapy, allied health and science programs at The University of Newcastle, and serves as a reviewer for medical and physiotherapy journals.

**Professor Geoff Mitchell** is Professor of General Practice and Palliative Care. His main research interest is in the role of General Practitioners in palliative care. His other research interests are in GP management of chronic and complex conditions including Pain and Attention Deficit Hyperactivity Disorder, and in quality issues in General Practice. He has authored over 140 refereed journal articles, as well as numerous book chapters and reports in these and other areas of clinical general practice. He also heads a research program utilising n-of-1 trial design for the evaluation of treatments in patient groups with small numbers, or people who are difficult to retain in more standard treatment trials. He was awarded his PhD in May 2005.

### Contact Information

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#### Study Team

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