**Pregabalin for acute whiplash study**

**Participant information sheet**

**Investigators**

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* Dr Sam McLean Research Vice Chair, Department of Anesthesiology, University of North Carolina, USA.
* Prof Stephan Schug,Chair of Anaesthesiology, School of Medicine and Pharmacology, The University of Western Australia
* Prof Geoff Mitchell, Professor of General Practice and Palliative Care, The University of Queensland
* Prof Steve Gibson, Deputy Director of National Aging Research Institute and Director of Research, Caulfield Pain Management and Research Centre.
* Prof Luke Connelly, Professor of Health Economics, The University of Queensland
* Dr Gerben Keijzers, Associate Professor, Griffith University and Staff Specialist, Emergency Department, Gold Coast University Hospital
* Dr Jane Nikles, Senior Research Fellow, RECOVER Injury Research Centre, The University of Queensland.
* Dr John Leou, Intern, Gold Coast University Hospital
* Dr Eric Richman, ED physician, Ipswich Hospital.
* Dr Peter Scott, GP, Griffith Health and Medical Services.
* Prof Rob Ware, Professor of Statistics. Griffith University

Thank you for your interest in joining our study which aims to find out whether pregabalin if given early in acute whiplash, can prevent the chronic pain that can develop after a neck injury.

Over many years researchers at Recover Injury Research Centre, , The University of Queensland have been working to develop more effective treatments for whiplash injuries. Pregabalin is an anticonvulsant and neuropathic [pain](http://www.drugs.com/cdi/pregabalin.html) agent which has promise for treating acute whiplash injury and preventing the development of chronic pain. Exactly how pregabalin works is not known. It is thought to bind to certain areas in the nervous system that help reduce seizures, nerve pain, and anxiety. Further information about pregabalin, including its possible side effects, can be found at the end of this information sheet. We now need to test the effectiveness of pregabalin for treating whiplash in a formal trial.

***We do not know if the addition of pregabalin to advice about how to manage your whiplash will be any better than placebo plus advice for people with acute whiplash. We are asking you to help us find out the answer to this question. Everyone will be receiving the best evidence-based treatment we know about so far, which is the advice contained in the booklet you will be given about how to recover from whiplash. This is the case even if you are randomised to the placebo group.***

**Process of the Study**

Prior to entry into the study, the results of your baseline questionnaires will be reviewed to determine your eligibility to participate in the trial. You will be notified as to whether you meet the criteria to be in the study by one of our research staff shortly following your completion of the initial questionnaires. You may be advised to seek further medical attention from your GP if indicated.

If you fit the criteria, you will be given an envelope containing the trial medication to take home with you. The medication will be either active pregabalin or a dummy tablet – called placebo – that is inactive. All participants will be given a booklet containing general advice for people who have suffered a whiplash injury. Our trial doctor will call you every three days and then weekly to see how you are and to adjust your medication dose. If you would like to, we can arrange a visit to a local GP during the time you are taking the trial medication, at no cost to you. During the trial you will fill out a symptom diary in which you will also record other treatments and medication taken. After 5 weeks you will stop the medication. Then there will be questionnaires to fill out at 5 weeks after starting the trial, and at 3, 6 and 12 months later.

So the study will require a minimum 12 months commitment from you, including the first assessment and follow up assessments at 5 weeks, 3, 6 and 12 months. If you volunteer to participate in this study, you will be required to complete follow-up assessments. At each assessment you will be asked to complete some questionnaires about your neck pain and experiences with whiplash and the accident. Each assessment will take approximately one hour of your time.

Details of the questionnaires are as follows:

**Questionnaires**

You will be asked to complete a series of baseline questionnaires seeking information on the accident history, current symptoms, any treatment received to date, and employment status. You will also be asked to complete questionnaires about your neck pain and general health.

**Interventions and followup**

After the initial assessment, you will be randomly allocated to the ‘pregabalin plus advice’ group or the ‘placebo plus advice’ group. The treatment period is for a maximum of 5 weeks with a follow up over 12 months *and this will be at no personal financial cost to you*. All assessments will be accessible for completion online at 5 weeks, and 3, 6 and 12 months.

You should let your GP know you are taking part in this trial, and if extra medications are being prescribed please let the research team know prior to starting. There is also an information sheet for your GP that you will be given at the start of the study.

**What should do if I have any concerns about medication side effects?**

If you have any concerns about the medication please contact the study doctor on the phone number 0408 599 033.

If you have any problems with the medication you will be advised to stop the trial medication.

**Can I talk to a doctor after hours if I feel I need to?**

One of the study doctors carries a mobile phone that that you can call 24hrs if you have any urgent concerns. The phone number is 0408 599 033. If you are unable to get in touch with anyone then do not take the medication until you have been able to speak to one of the study researchers.

**Pregnancy**

The effects of pregabalin on the unborn child and on the newborn baby are not known. Because of this, it is important that research project participants are not pregnant or breast-feeding and do not become pregnant during the course of the research project. You must not participate in the research if you are pregnant or trying to become pregnant, or breast-feeding. If you are female and child-bearing is a possibility, you will be required to undergo a pregnancy test prior to commencing the study.  If you are male, you should not father a child or donate sperm for at least 1 month after the last dose of study medication.

Both male and female participants must avoid pregnancy during the course of the research and for a period of 1 month after completion of the study.  You should discuss effective methods of avoiding pregnancy with your study doctor.

*[For female participants]* If you do become pregnant whilst participating in the research project, you should advise the study doctor immediately. Your study doctor will withdraw you from the research project and advise on further medical attention should this be necessary. You must not continue in the study if you become pregnant.

*[For male participants]* You should advise the study doctor (Dr Jane Nikles 0408 599 033) if you father a child while participating in the study. Your study doctor will advise on medical attention for your partner should this be necessary.

**Other information**

Clinicians associated with the ongoing management of study participants will continue to provide care and support that they deem is in the patient’s best interests at all times (National Statement S1.7).

You may benefit from being in either group. While it is possible that you may receive no direct benefit from this trial, the knowledge gained from your participation may benefit others in the future. Remember there is no obligation to take part in the study and you are free to withdraw from the study at any time, with or without stating a reason.

The results of your assessment and your responses to treatment will remain confidential at all times and will not be released to a third party without your written permission or as required by law. The assessments will be stored securely at The University of Queensland. The data will be de-identified, so that no one will be able to tell who the data belongs to, except the research team. The result of this study will be published but your identity will never be revealed.

This study adheres to the Guidelines of the ethical review process of The University of Queensland and the National Statement on Ethical Conduct in Human Research. The researchers will provide care and support that they deem is in your best interests at all times (*National Statement S1.7*).

Whilst you are free to discuss your participation in this study with the project director (Professor Michele Sterling contactable on 0488 196 862), if you would like to speak to an officer of the University not involved in the study, you may contact the Ethics Coordinator on 3365 3924 (UQ).

Any concerns or complaints about the conduct of this study should be directed to the:

                                   HREC Secretary

                                   Gold Coast University Hospital

                                   1 Hospital Boulevard

                                   SOUTHPORT   QLD   4215

                                   Email: GCHEthics@health.qld.gov.au

Any complaint will be investigated promptly and you will be informed of the outcome.

**Principal Investigator:**

Professor Michele Sterling

Chief Investigator

Director of the NHMRC Centre of Research Excellence in Recovery Following Road Traffic Injuries and Associate Director of RECOVER Injury Research Centre

The University of Queensland

**Information about pregabalin (Lyrica)**

**What Lyrica is used for**

Lyrica is used to treat neuropathic pain, which is pain caused by an abnormality of, or damage to, the nerves. Lyrica is also used to control epilepsy. Epilepsy is a condition where you have repeated seizures (fits). There are many different types of seizures, ranging from mild to severe. Lyrica belongs to a group of medicines called anticonvulsants. These medicines are thought to work by controlling brain chemicals which send signals to nerves so that seizures do not happen. Lyrica also has pain relieving effects. Lyrica may be used alone, or in combination with other medicines, to treat your condition. Your doctor may prescribe Lyrica in addition to your current therapy when your current treatment is no longer working as well as before. **Ask your doctor if you have any questions about why Lyrica has been prescribed for you.** Your doctor may have prescribed it for another reason. This medicine is available only with a doctor's prescription.

**Before you take Lyrica**

***When you must not take it***

**Do not take Lyrica if you have an allergy to:** • pregabalin, the active ingredient in Lyrica, or • any of the ingredients listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include: • shortness of breath, wheezing or difficulty breathing • swelling of the face, lips, tongue or other parts of the body • rash, itching or hives on the skin.

**Do not take this medicine after the** **expiry date printed on the pack or if the packaging is torn or shows signs of tampering.** If the capsules have expired or the pack is damaged, return to your pharmacist for disposal.

**If you are not sure whether you should start taking this medicine, talk to your doctor.** take Lyrica, your doctor can help you decide whether or not to take it during pregnancy. **Tell your doctor if you are breastfeeding or plan to breast-feed.** The active ingredient in Lyrica passes into breast milk and its safety in infants is unknown. It is recommended that you do not breastfeed while taking Lyrica. **If you have not told your doctor about any of the above, tell them before you start taking Lyrica.**

***Taking other medicines***

**Tell your doctor or pharmacist if you are taking any other medicines, including:** • all prescription medicines • all medicines, vitamins, herbal supplements or natural therapies you buy without a prescription from a pharmacy, supermarket, naturopath or health food shop. Some medicines may be affected by Lyrica or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines. Your doctor will advise you.

**Tell your doctor or pharmacist if you are taking any of the following:** • oxycodone, morphine or codeine, pain relievers called opioid analgesics • lorazepam, a medicine used to treat anxiety • medicines used to treat allergies (antihistamines) • medicines used to treat certain psychiatric disorders. Taking these medicines together with Lyrica may increase your chance of experiencing side effects. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor or pharmacist will advise you.

***Before you start to take it***

**Tell your doctor or pharmacist if you have allergies to:** • any other medicines, especially barbiturates or any other anticonvulsant medicines • any other substances, such as foods, preservatives or dyes. **Tell your doctor if you have or have had any of the following medical conditions:** • congestive heart failure • hereditary problems with galactose metabolism • kidney problems • diabetes • a history of substance abuse • depression.

**Tell your doctor if you have a** **history of substance abuse.** There have been reported cases of misuse and abuse with Lyrica.

**Tell your doctor if you are** **pregnant or plan to become pregnant.** Lyrica is not recommended for use during pregnancy. However, if you have epilepsy, it is very important to control your fits while you are pregnant.

**How to take Lyrica**

**Follow all directions given to you by your doctor carefully.** They may differ from the information contained in this leaflet. **If you do not understand the instructions on the box, ask your doctor or pharmacist for help.**

***How much to take***

Your doctor will tell you how many capsules you need to take each day. This may depend on your age, your condition and whether or not you are taking any other medicines. Your doctor may recommend that you start with a low dose of Lyrica and slowly increase the dose to the lowest amount needed to control your epilepsy/convulsions or neuropathic pain. The usual dose range is 150 mg per day to 600 mg per day given in two divided doses.

***How to take it***

**Swallow the capsules whole with a full glass of water.**

***When to take it***

**Take your medicine at about the same time each day.** Taking it at the same time each day will have the best effect. It will also help you remember when to take it. It does not matter if you take this medicine before or after food.

***How long to take it*** **Continue taking your medicine for as long as your doctor tells you.** This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine, even if you feel well. **Do not stop taking Lyrica, or lower the dosage, without checking with your doctor. Do not let yourself run out of medicine over the weekend or on holidays.** Stopping Lyrica suddenly may worsen your condition or cause unwanted effects such as sleeplessness, headache, nausea (feeling sick), anxiety, excessive sweating or diarrhoea (runny stools). If appropriate, your doctor will slowly reduce your dose before you can stop taking it completely.

***If you forget to take it***

**If it is almost time for your next dose (within 4 hours), skip the dose you missed and take your next dose when you are meant to.** **Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.** **Do not take a double dose to make up for the dose that you missed.** This may increase the chance of you getting an unwanted side effect. **If you are not sure what to do, ask your doctor or pharmacist.** **If you have trouble remembering to take your medicine, ask your pharmacist for some hints.**

***If you take too much (overdose)***

**Immediately telephone your doctor or the Australian Poisons Information Centre (telephone 13 11 26) or the New Zealand National Poisons Information Centre (telephone 0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Lyrica. Do this even if there are no signs of discomfort or poisoning.** You may need urgent medical attention. Symptoms of an overdose with Lyrica may include mood changes, feeling tired, confusion, depression, agitation and restlessness.

**While you are taking Lyrica**

***Things you must do***

**If you are about to be started on any new medicine, remind your doctor, dentist or pharmacist that you are taking Lyrica.** **Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.** **If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.** It may affect other medicines used during surgery.

**Tell your doctor immediately if you experience any changes in your vision.** Lyrica may cause blurring or other changes in eyesight. Your doctor may ask you to stop taking Lyrica to improve these symptoms.

**Tell your doctor immediately if you have any thoughts of suicide or self-harm, any unusual changes in mood or behaviour, or show signs of depression.** Some people taking medicines to treat convulsions, such as Lyrica, have had thoughts of harming themselves or taking their life. **Patients and caregivers should be alert and monitor for these effects.**

**Signs and symptoms of suicidal risk include:** • thoughts or talk of death or suicide • thoughts or talk of self-harm or harm to others • any recent attempts of self-harm • new or an increase in aggressive behaviour, irritability or agitation • new or worsening depression. Mention of suicide or violence must be taken seriously. **If you or someone you know is demonstrating these warning signs of suicide while taking Lyrica, contact your doctor or a mental health professional right away.** **Tell your doctor if you feel Lyrica is not helping your condition.** Your doctor may need to change your medicine.

**Tell your doctor if, for any reason, you have not taken Lyrica exactly as prescribed.** Otherwise, your doctor may change your treatment unnecessarily. **If you become pregnant while taking Lyrica, tell your doctor immediately.** **Keep all of your doctor's appointments so that your progress can be checked.** Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

***Things you must not do***

Do not take Lyrica to treat any other complaints unless your doctor tells you to. **Do not give your medicine to anyone else, even if their symptoms seem similar to yours or they have the same condition as you.** **Do not stop taking your medicine or lower the dosage without checking with your doctor.**

***Things to be careful of***

**Be careful driving or operating machinery until you know how Lyrica affects you.** As with other anticonvulsant medicines, Lyrica may cause dizziness and drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous. **Be careful when drinking alcohol while you are taking this medicine.** If you drink alcohol, symptoms such as dizziness and drowsiness may be worse.

**Side effects**

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Lyrica.** Lyrica helps most people with neuropathic pain or epilepsy, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects. It can be difficult to tell whether side effects are the result of taking Lyrica, effects of your condition or side effects of other medicines you may be taking. For this reason it is important to tell your doctor of any change in your condition. If you are over 65 years of age you may have an increased chance of getting side effects. **Do not be alarmed by the list of side effects.** You may not experience any of them. **If you get any side effects, do not** **stop taking Lyrica without first talking to your doctor or pharmacist.** **Ask your doctor or pharmacist to answer any questions you may have.**

***Tell your doctor if...***

**Tell your doctor or pharmacist if you notice any of the following and they worry you:** • dizziness • feeling tired or drowsy • constipation • diarrhoea • nausea • headache • increase in weight • unsteadiness when walking, reduced co-ordination, shaking or tremors • dry mouth • blurred or double vision. The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

***Tell your doctor as soon as possible if...***

**Tell your doctor as soon as possible if you notice any of the following:** • unusual changes in mood or behaviour • signs of new or increased irritability or agitation • signs of depression • swelling of the hands, ankles or feet • enlargement of breasts • unexplained muscle pain, tenderness and weakness • passing little to no urine. The above list includes serious side effects that may require medical attention. Serious side effects are rare.

***Go to hospital if...***

**Tell your doctor immediately or go to Accident and Emergency at your nearest hospital, if you notice any of the following:** • shortness of breath, swelling of the feet and legs, weight increase due to fluid build-up • irritated red eyes that are sensitive to light • more frequent or more severe seizures (fits) • sudden signs of allergy such as rash, itching or hives, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or difficulty breathing. The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare. **Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.** Other side effects not listed above may also occur in some people. Some of these side effects (for example, changes in blood pressure) can only be found when your doctor does tests from time to time to check your progress.

**After taking Lyrica**

***Storage***

**Keep your capsules in the pack until it is time to take them.** If you take the capsules out of the pack they may not keep well. **Keep your capsules in a cool dry place where the temperature stays below 25°C.** **Do not store Lyrica or any other medicine in the bathroom or near a sink. Do not leave it on a windowsill or in the car on hot days.** Heat and dampness can destroy some medicines. **Keep it where children cannot reach it.** A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

***Disposal***

**If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.**

***Ingredients*** **Active Ingredients** 75 mg capsules - 75 mg pregabalin. It also contains: • Lactose • Maize starch • Purified talc • Gelatin • Titanium dioxide • Sodium lauryl sulfate • Colloidal anhydrous silica • Red iron oxide CI77491