easternhealth

Participant Information Sheet/Consent Form

Non-Interventional Study - *Adult providing own consent*

Eastern Health – Box Hill

Title	Comparative Persistence with Prolia® and Weekly Alendronate in 6 Asia-Pacific countries: A Prospective Observational Study
Protocol Number	20180100
Local Sponsor	IQVIA RDS Pty. Limited
Global Sponsor	Amgen Asia Holdings Limited
Principal Investigator	Professor Christopher Gilfillan
Location	Eastern Health – Box Hill

Part 1 What does my participation involve?

This Participant Information and Consent Form is 11 pages long, please make sure you have all the pages of this document.

1 Introduction

You are invited to take part in this observational research project because you:

- are a woman who has gone through menopause
- have been diagnosed with osteoporosis
- are currently being prescribed either Prolia® or alendronate by your regular doctor (who may also be the study doctor).

The primary objective of this research is to collect data regarding the comparison of persistence with Prolia® to persistence with weekly alendronate for the management of postmenopausal women with osteoporosis. Osteoporosis is a disease that causes bones to become weak and brittle.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and research involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or local doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

• Understand what you have read
• Consent to take part in the research project
• Consent to the tests and research that are described
• Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

Throughout this document, “study doctor” refers to your regular doctor who has been treating you for your osteoporosis and will continue to treat you during this study.

2 What is the purpose of this research?

All potential new medications are initially tested in clinical studies to see how safe they are and how well they work. The health authorities then review the results of these studies to decide whether the potential new medication should be approved for use. Once it is approved, doctors and the health authorities continue to monitor the people taking the medication to learn more about its use in everyday life. This may include finding out about possible new side effects that were not seen before or finding out whether patients are taking the medication correctly and as prescribed by their doctor.

This study is “observational”, which means it will follow routine clinical practice and will not interfere with the normal care you receive in any way. There are no additional procedures required for people taking part in this study.

The purpose of this study is to collect more information about two medications, called “denosumab” (Prolia®) and “alendronate”.

Both medications are approved in Australia by the Therapeutic Goods Administration and also used by doctors worldwide for the treatment of osteoporosis.

However, in countries of the Asia-Pacific region, not enough studies have been done to compare both medications in terms of how long patients continue to take them from when they are first prescribed. This is called “treatment persistence”.

This study will collect information about treatment persistence with each of these medications among women with osteoporosis who have gone through menopause (postmenopausal).

This research is being conducted by Amgen Asia Holdings Limited and sponsored in Australia by IQVIA RDS Pty. Limited.

What are the medications used in this study and how do they work?
Osteoporosis is a bone disease that occurs when the body loses too much bone, makes too little bone, or both. As a result, bones become weak and may break from a fall or, in more serious cases, from sneezing or minor bumps.

The medications used in this study (Prolia® and alendronate) increase the thickness of bone (bone mineral density) by slowing down the cells that usually break down bone (osteoclasts). This allows the cells that build bone (osteoblasts) to work more efficiently and makes bones stronger.

Both Prolia® and alendronate are currently used to increase bone thickness in postmenopausal women, men with prostate cancer, and people with bone loss from long-term treatment with steroid medications (a type of medication used to fight inflammation).

Prolia® is given by injection (60 mg) under the skin of the thigh, abdomen or upper arm, once every 6 months. **If you are taking Prolia®**, the injections will be given by the study doctor.
Alendronate is provided in the form of white, oval, uncoated tablets. **If you are taking alendronate**, you will continue to take one 70 mg tablet once a week, on an empty stomach. The tablet should be swallowed whole with a full glass of plain water (**not** with mineral water, coffee, tea, or juice).

3 What does participation in this research involve?

Before taking part in this study, you will be given time to fully read and understand this information sheet and consent form. You will be given a chance to ask any questions that you might have before you make the decision. If the study is right for you and you decide to join the study, your participation will last for 2 years. During this time, you will attend your usual appointments with your regular doctor and will continue to take your osteoporosis medication, as prescribed by your doctor. However, for the purpose of this study, your doctor will need to collect additional information during some of your regular appointments. This information will be collected on 3 occasions:

- right after you join the study
- 1 year after you join the study
- 2 years after you join the study

During the study, some or all the following information will be collected when you go to see your doctor:

- your age, gender and race
- height and weight
- smoking history
- history of osteoporosis, including information about any bone fracture you or your parents had
- prior osteoporosis medications and oral glucocorticoids (medical tablets used for pain relief)
- vitamin D and calcium supplements you are currently taking
- bone mineral density (how much calcium and other types of minerals are in your bones; it reflects the strength of your bones). This information will be collected from bone scans you receive as part of your routine visit.
- details about whether you are being reimbursed for your osteoporosis medication (Prolia® or alendronate)
- dates of Prolia® administration (if you are receiving this medication)
- date, dose, quantity of alendronate, and number of alendronate prescriptions given to you (if you are taking this medication)
- side effects (if any) from your osteoporosis medication (Prolia® or alendronate).

It is desirable that your local doctor be advised of your decision to participate in this research project.

What treatment will you receive?
This is an observational study; therefore, no medications or other treatments are provided to you by the Sponsor as part of this study. The medication you receive during this study is being prescribed to you by your regular doctor as part of your regular medical care and is not being given to you as part of this study. You will not receive any treatment specifically for this study.

Do I have to pay, or will I be paid to take part in the study?
Since you are following your normal clinical routine and standard of care, there is no charge for you to take part, and you will not be paid for taking part in this study.

4 What do I have to do?

You do not need to do anything different for this study. Simply visit the study doctor for your routine visits and continue to take your regular osteoporosis medication as prescribed by them.

During the study, it is important that you tell the study doctor about any additional medications you are taking, as well as any unusual symptoms that you experience during the study.

If you are participating, or have participated within the past 6 months, in another clinical study involving any investigational medication or procedure, you should discuss this with the study doctor to see if you can still be in this study.

Inform the study doctor if you wish to withdraw from the study.

If you are taking alendronate, you will need to bring your used and unused medication (including empty containers of the used medication) to the study centre for each visit (right after you join the study, 1 year after, and again 2 years after you join the study).

5 Other relevant information about the research project

It is anticipated that about 924 women will participate in this study, approximately 154 patients per country will be enrolled. The study will take place in Australia, Taiwan, South Korea, Hong Kong, Singapore, and Thailand.

6 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with Eastern Health.

If you withdraw your consent to take part in this study, the data collected prior to your withdrawal will be processed along with other data collected as part of the study.

7 What are the alternatives to participation?

Your study doctor will discuss with you any other treatments, or investigational drugs or treatments, that may be available to you and will also discuss their risks and benefits. If you decide not to take part in this study, it will not affect your ability to receive medical care. You will still be able to receive the medication if you decide not to take part in this study.

8 What are the possible benefits of taking part?

Since this study is observational, it will not change how your treatment is managed by your doctor. There are no direct risks and benefits to taking part in the study. Nevertheless, participating in this study may lead to an improved understanding of your condition. The findings from this study will be used to give healthcare providers important information that may help to improve the future treatment of postmenopausal women with osteoporosis in the six Asia-Pacific countries where this study is taking place.

9 What are the possible risks and disadvantages of taking part?

While this research does not involve any interventional treatment, you may be receiving medical treatments that cause side effects. If you have any of these side effects, or are worried about them, talk with your study doctor. Your study doctor will also be looking out for side effects.

There may be side effects that the researchers do not expect or do not know about and that may be serious. Tell your study doctor immediately about any new or unusual symptoms.

Many side effects go away shortly after treatment ends. However, sometimes side effects can be serious, long lasting or permanent. If a severe side effect or reaction occurs, your doctor may need to stop your treatment. Your doctor should discuss the best way of managing any side effects with you. This study does not require you to take any medication aside from the treatment that you are receiving in routine practice as prescribed by your regular doctor. Therefore, there are no foreseeable physical risks to you associated with your participation in this study.

There is a low risk of loss of confidentiality of your personal information; however, steps have been taken to help ensure this will not happen. You will read more about the protection of your information later in Section 15.

10 Does this research project involve collection of tissue?

This research project does not involve the collection of tissue (including blood or urine).

11 What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the medications involved. If this happens, your study doctor will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, your study doctor will make arrangements for your regular health care to continue. If you decide to continue in the research project you will be asked to sign an updated consent form.

Also, on receiving new information, your study doctor might consider it to be in your best interests to withdraw you from the research project. If this happens, he/ she will explain the reasons and arrange for your regular health care to continue.

12 What if I withdraw from this research project?

If you do withdraw your consent during the research project, please notify a member of the research team before you withdraw. A member of the research team will inform you if there are any special requirements linked to withdrawing. The study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the sponsor up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

13 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include unacceptable side effects; if the study is no longer in the patient's best interest; or sponsor termination of the study at any time.

14 What happens when the research project ends?

As this is an observational study only, treatment will still be available after the research project finishes. After completion, your study doctor will continue with your regular health care.

Part 2 How is the research project being conducted?

15 What will happen to information about me?

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Your personal information collected and used during the study may include sensitive information about your physical or mental health or condition, health information about you in medical records, and other personal information such as your age, gender and race. Any information obtained in connection with this research project that can identify you will remain confidential.

Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form you agree to the research team accessing health records if they are relevant to your participation in this research project.

Your medical files will be reviewed at the hospital (or study doctor's office) in order to check the information and verify the clinical study procedures, without breaking your confidentiality.

All information which is collected about you in records that leave the study centre for the purposes of medical, laboratory, statistical or regulatory activities related to the study research will be identified by your study participant number. Your age and gender will also be included.

The Sponsor will store your coded data as long as it is required, as part of safety profile and for regulatory agency requests. After this period the data will be destroyed. Before any external use for scientific research and publications, your personal data will be anonymised. That means you will not be identified with this data. At the hospital (or study doctor's office) your coded personal data will be retained and used for up to five (5) years.

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored in accordance with Australian privacy laws for a minimum of 15 years after the completion of the research project

Information about your participation in this research project may be recorded in your health records.

Your health records and any information obtained during the research project are subject to inspection for the purpose of verifying the procedures and the data. This review may be done by the relevant authorities and authorised representatives of the global and local Sponsors, Amgen Asia Holdings Limited and IQVIA RDS Pty. Limited, the institution relevant to this Participant Information Sheet, Eastern Health, or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant research personnel and regulatory authorities as noted above.

You are also giving permission for the processing of your personal information or any part of it to be transferred to people and organisations outside your country, where personal data protection laws

may be less strict. You may use your rights under your local data protection laws to access and correct your personal information or ask for it to be deleted.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to request access to the information collected and stored by the research team about you. You also have the right to request that any information with which you disagree be corrected. Please contact the research team member named at the end of this document if you would like to access your information.

The information from the study may be published or sent to regulatory authorities or health insurers in your country or other countries where regulatory approval or payment for the medication is required. Your identity will not be released except with your permission, unless necessary for the vital interests of your safety.

16 Complaints and compensation

If you have a question, concern or complaint about any part of this study, you should ask to speak to the study doctor or a member of the research team. They will do their best to help (see Section 20 for further details).

If you have any questions about your rights as part of the research, or any concerns or complaints about the research that you do not want to discuss with the study doctor or research team, please also see Section 20 for further details.

17 Who is organising and funding the research?

This research project is being conducted by Amgen Asia Holdings Limited and sponsored in Australia by IQVIA RDS Pty. Limited.

Eastern Health will receive a payment from IQVIA RDS Pty. Limited. for undertaking this research project.
No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

18 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of The Royal Melbourne Hospital.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

19 Further information and who to contact

The person you may need to contact will depend on the nature of your query.
If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal study doctor on 9092 6753 or any of the following people:

Clinical contact person

Name	Andriana Chronopoulos
Position	Clinical Trials Coordinator
Telephone	9094 9510
Email	andriana.chronopoulos@monash.edu

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person

Name	Eastern Health Office of Research and Ethics
Position	Manager
Telephone	03 9895 3398
Email	ethics@easternhealth.org.au

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	Melbourne Health HREC
HREC Executive Officer	Manager HREC
Telephone	(03) 9342 8530
Email	Research@mh.org.au

Local HREC Office contact (Single Site -Research Governance Officer)

Name	Eastern Health Office of Research and Ethics
Position	Manager
Telephone	03 9895 3398
Email	ethics@easternhealth.org.au

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Consent Form - *Adult providing own consent*

Title	Comparative Persistence with Prolia® and Weekly Alendronate in 6 Asia-Pacific countries: A Prospective Observational Study
Protocol Number	20180100
Local Sponsor	IQVIA RDS Pty. Limited
Global Sponsor	Amgen Asia Holdings Limited
Principal Investigator	*A/Professor Christopher Gilfillan*
Location	*Eastern Health – Box Hill*

Declaration by Participant

- I am 18 years or older.
- I have read the Participant Information Sheet or someone has read it to me in a language that I understand.
- I understand the purpose, procedures and risks of the research described in the project.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future health care.
- I understand that I will be given a signed copy of this document to keep.
- I agree if my study doctor is not my family doctor, my family doctor may be told about my taking part in this study and asked for medical information about me.
- I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Eastern Health concerning my condition and treatment for the purposes of this project. I understand that such information will remain confidential.
- I give permission for my personal information, including age, race and ethnicity to be collected and used as part of this clinical study and to be:
    - identified only with my participant ID number;
    - reviewed, processed and disclosed by and to the Sponsor and its authorised representatives and study monitors for the purposes described in the study protocol;
    - reviewed or audited by the appropriately authorised organisations;
    - published and sent to regulatory authorities or health insurers in my country or other countries; and
    - transferred, if required, to any country, where laws protecting my personal information may be less strict.
- I understand I may also be contacted at a later date(s) for my permission in connection with this study or any related sub-study

By signing this document, I agree to take part in this study, as set out in this information sheet and consent form.

Name of Participant (please print) _____

Signature _____ Date _____

Under certain circumstances (see Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 at 4.8.9*) a witness* to informed consent is required*

Name of Witness* to
Participant's Signature (please print) _____

Signature _____ Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

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Form for Withdrawal of Participation - *Adult providing own consent*

Title	Comparative Persistence with Prolia® and Weekly Alendronate in 6 Asia-Pacific countries: A Prospective Observational Study
Protocol Number	20180100
Local Sponsor	IQVIA RDS Pty. Limited
Global Sponsor	Amgen Asia Holdings Limited
Principal Investigator	Professor Christopher Gilfillan
Location	Eastern Health Box Hill

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with Eastern Health.

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.