

**Effects of Intravitreal Ranibizumab for Macular Edema With  
Nonproliferative Diabetic retinopathy**

( NCT02834663 / CRFB002DKR03T )

**Informed Consent Form**

**Edition Number : 1.0 Edition**

**Generation Date : Jan 18, 2017**

**Principal Investigator : Yun-sik Yang**

**Research Institute : NOVARTIS KOREA LTD. And WONWANG UNIVERSITY HOSPITAL**

# Informed Consent Form

This research officer will agree to participate in clinical research from you and follow relevant regulations when documenting it and will follow legal procedures based on ethical principles based on the Helsinki Declaration.

You should read this consent carefully before deciding whether or not to participate in this study. It is important that you understand why this study is being done and what it is doing. You can ask any question as you read this document describing this study. Please decide with sufficient time. Please ask as many questions as you need to decide whether or not to participate in this study.

When you have answered all of your questions and have decided that you would like to participate in this study, please sign this document to begin participating in this study. You and the person responsible for the study who described this document (or someone authorized by the person responsible for research) must sign this form and write the date in hand.

Your signature means that you have been told about this clinical study. In addition, your signature on this document means that you (or your legal representative) want to participate in this study.

It is important to read and understand this manual before agreeing to participate in this study. This manual describes the purpose, procedure, benefit, risk, discomfort and caution of this study. It also describes the subject's right to stop participating in the study at any time. It is very important that the study subject properly informs the doctor of all of his or her past medical history, so during this study the doctor should do his best to ensure that the study is conducted in the safest way possible.

Before signing the consent form, please take sufficient time to consider and read the manual, and if necessary, consult with your family or others.

## Research Background

Diabetic retinopathy is a major disease that causes macular edema and angiogenesis, leading to acquired blindness after the 20s. The prevalence of type 2 diabetes is increasing in the younger generation, which means an increased risk of retinopathy impairing vision.

There is microvascular perfusion in early diabetic retinopathy and many recent studies have reported that it is associated with clinical macular edema of mild to moderate non-proliferative diabetic retinopathy. In addition, many studies report that the number and turnover rate of microvascular perfusion are important prognostic factors for estimating the progression and regression of diabetic retinopathy. This decrease, which indicates that the regression of diabetic retinopathy and its therapeutic effect.

### **Purpose of the research**

To evaluate the effect of Ranibizumab injection on microvascular changes in eyes with mild to moderate non-proliferative diabetic retinopathy with macular edema

### **Research Participation**

Participation in research is voluntary. If you refuse to participate in the study or decide to stop participating, you will not have any negative impact on your future medical care. We will also notify you of any changes in the progress of our research that may affect our willingness to participate.

The researcher or regulatory agency may terminate the study early. Upon early termination, the research physician will notify you immediately and explain the reason for the termination. In this case, your information recording and information collection will be stopped during the study, but normal standard treatment will continue.

### **Study Period, Procedure and Method**

When first enrolled in the target patient group, after initial evaluation, a visit to the ophthalmologist is conducted every month to perform Ranibizumab injections and basic ophthalmology examinations (for a total of 6 months). Inject mg. Fluorescent fundus angiography and light coherence tomography are performed at the initial evaluation and at 3 months and 6 months, the last visit. Fluorescent fundus angiography and fundus photography are analyzed to evaluate microvascular changes (microvascular, non-perfused areas, hard exudates, cotton patches). In addition, we investigate whether the central macular thickness, adverse reactions, etc.

## **Research Risk**

There is no risk associated with participating in the study beyond the risks of general testing and treatment. For fluorescein angiography, you are given a fluorescent dye injection into your vein (which glows green when exposed to certain types of light). Risks associated with fluorography (dye examination) may include bleeding and bruising at the injection site, nausea and sometimes vomiting. Mild reactions, such as itching, edema, or redness at or around the injection site, occur about 1 out of every 100 times. Allergic reactions to more severe fluorescent dyes (contrast agents) can also occur: this includes severe edema and dyspnea, which can occur in 1 in 10,000 people. Fluorescent dye injections can cause heart attack, stroke, or death in about 1 in 222,000 people. If you have had a severe allergic reaction to fluorescent dyes before, you cannot participate in this clinical study.

## **Research Benefits**

Study subjects participated in this study and received a total of 6 intravitreal injections of ranibizumab once a month. Even if you don't participate, you will receive general testing and treatment. The results of this study will contribute to making guidelines for diagnosis and treatment of patients similar to those of the future study.

## **Cost and compensation**

Ranibizumab injections (0.5 mg) given at each visit are provided free of charge by Novartis. In addition, inspection fees (light coherence tomography, fluorescein angiography examination) and transportation expenses are provided for each visit.

## **Subject's Compliance**

Initial evaluations and monthly visits to the hospital are required to conduct surveys and eye exams. You should also report any abnormal symptoms to your research doctor or research staff.

## **Privacy**

If you participate in this study, this study collects your personal information (names are recorded as initials and managed by a study management number. Personal identification information and health information, etc.). The personal information collected in this way is strictly managed in accordance with relevant laws and regulations, and only the personnel involved in the research, health authorities, and sponsors' inspectors can access the collected data. Personally identifiable information among collected personal information is not directly used or necessary for research, but is used only for the purpose of linking you with clinical data obtained through research. In addition, the personal identification list is kept and transferred to the IRB for up to three years after the study is conducted. Your personal information will be used until the research purpose is achieved, and the collected information will be properly managed in accordance with the Personal Information Protection Act.

Whether or not to participate in this study is entirely at your option and there will be no penalty for not participating. In addition, even after consenting to participate, if you wish to withdraw your consent, you can request that the investigated data be discarded. In this case, all materials except for the information and resources already used in the study will be disposed of in accordance with legitimate procedures.

The collected data is integrated with data obtained from other participants in the study, and the results can be used as a scientific basis, including referrals at the time of study, publication or meeting. Your identity will not be disclosed if a publication or report on the results of this study is published.

## **Inquiries**

As a participant in this study, you may contact the Institutional Bioethics Committee (063 859 2232) if you have any questions about your rights, if you have any questions related to the study, or if you suspect any adverse reactions have occurred.

\* If you have any questions about this study, or if there is any danger, inconvenience, or damage, please contact the above researchers.

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- I understand that my personal information is not used for any purpose other than research and is confidential.
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Signer's signature: \_\_\_\_\_ Date of signature : 2016.8.1

Signature by legal agent (if necessary): \_\_\_\_\_ Date of signature : \_\_\_\_\_

Witness signature (if necessary): \_\_\_\_\_ Date of signature : \_\_\_\_\_

We have read and explained the informed consent to the subject, and then answered all the questions he/she has raised. Him/herself has also already understood and agreed to participate in the scientific research.

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Signer's signature: \_\_\_\_\_ Date of signature : 2016.8.11

Signature by legal agent (if necessary): \_\_\_\_\_ Date of signature : \_\_\_\_\_

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Signatures of researchers : 0502K Date of signature : 2016.8.11

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Signer's signature: \_\_\_\_\_  \_\_\_\_\_ Date of signature : 2016. 9. 12

Signature by legal agent (if necessary): \_\_\_\_\_ Date of signature : \_\_\_\_\_

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Signer's signature: DR Kim Date of signature : 2016.10.20

Signature by legal agent (if necessary): \_\_\_\_\_ Date of signature : \_\_\_\_\_

Witness signature (if necessary): \_\_\_\_\_ Date of signature : \_\_\_\_\_

We have read and explained the informed consent to the subject, and then answered all the questions he/she has raised. Him/herself has also already understood and agreed to participate in the scientific research.

Signatures of researchers : OK OK Date of signature : 2016.10.20



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Signer's signature: \_\_\_\_\_ Date of signature : 2016.12.14

Signature by legal agent (if necessary): \_\_\_\_\_ Date of signature : \_\_\_\_\_

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Signatures of researchers : 양 오영 Date of signature : 2016.12.14

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Signer's signature:  Date of signature : 2016.12.29

Signature by legal agent (if necessary): \_\_\_\_\_ Date of signature : \_\_\_\_\_

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Signer's signature: \_\_\_\_\_

Date of signature : 2017.1.4

Signature by legal agent (if necessary): \_\_\_\_\_

Date of signature : \_\_\_\_\_

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Signatures of researchers : 05 02/03

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Signer's signature: \_\_\_\_\_

Date of signature : 2019. 1. 5

Signature by legal agent (if necessary): \_\_\_\_\_

Date of signature : \_\_\_\_\_

Witness signature (if necessary): \_\_\_\_\_

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Signatures of researchers : 양 오경

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Date of signature : \_\_\_\_\_

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Signatures of researchers : 08 0212 Date of signature : 2019.1.5



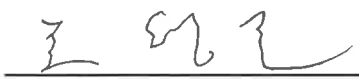
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Signer's signature:  Date of signature : 2017.3.13

Signature by legal agent (if necessary): \_\_\_\_\_ Date of signature : \_\_\_\_\_

Witness signature (if necessary): \_\_\_\_\_ Date of signature : \_\_\_\_\_

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Signer's signature:  Date of signature : 2017. 3.30

Signature by legal agent (if necessary): \_\_\_\_\_ Date of signature : \_\_\_\_\_

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Signer's signature: \_\_\_\_\_  \_\_\_\_\_ Date of signature : 2017.5.4

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- I may be able to access the personal information of participants to verify the reliability of the data and the procedure for conducting the research by the relevant personnel (monitoring personnel, inspectors, committees, and ministries related to government) within the scope of the related regulations. I know there is.
- I am free to request participation in the study and receive a copy of the consent form.

Signer's signature: \_\_\_\_\_  \_\_\_\_\_ Date of signature : 2017.5.29

Signature by legal agent (if necessary): \_\_\_\_\_ Date of signature : \_\_\_\_\_

Witness signature (if necessary): \_\_\_\_\_ Date of signature : \_\_\_\_\_

We have read and explained the informed consent to the subject, and then answered all the questions he/she has raised. Him/herself has also already understood and agreed to participate in the scientific research.

Signatures of researchers : OK  \_\_\_\_\_ Date of signature : 2017.5.29

## Informed Consent Signature Page

Research Title :

Effects of Intravitreal Ranibizumab for Macular Edema With Nonproliferative Dibetic retinopathy  
( NCT02834663 / CRFB002DKR03T )

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Signer's signature: \_\_\_\_\_ Date of signature : 2017.6.14

Signature by legal agent (if necessary): \_\_\_\_\_ Date of signature : \_\_\_\_\_

Witness signature (if necessary): \_\_\_\_\_ Date of signature : \_\_\_\_\_

We have read and explained the informed consent to the subject, and then answered all the questions he/she has raised. Him/herself has also already understood and agreed to participate in the scientific research.

Signatures of researchers : \_\_\_\_\_ Date of signature : 2017.6.14

## Informed Consent Signature Page

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( NCT02834663 / CRFB002DKR03T )

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I am free to request participation in the study and receive a copy of the consent form.

Signer's signature: \_\_\_\_\_

Date of signature : 2017.8.17

Signature by legal agent (if necessary): \_\_\_\_\_

Date of signature : \_\_\_\_\_

Witness signature (if necessary): \_\_\_\_\_

Date of signature : \_\_\_\_\_

We have read and explained the informed consent to the subject, and then answered all the questions he/she has raised. Him/herself has also already understood and agreed to participate in the scientific research.

Signatures of researchers : \_\_\_\_\_

Date of signature : 2017.8.17

## Informed Consent Signature Page

Research Title :

Effects of Intravitreal Ranibizumab for Macular Edema With Nonproliferative Diabetic retinopathy  
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Signer's signature: \_\_\_\_\_ Date of signature : 2017.9.6

Signature by legal agent (if necessary): \_\_\_\_\_ Date of signature : \_\_\_\_\_

Witness signature (if necessary): \_\_\_\_\_ Date of signature : \_\_\_\_\_

We have read and explained the informed consent to the subject, and then answered all the questions he/she has raised. Him/herself has also already understood and agreed to participate in the scientific research.

Signatures of researchers : OK [Signature] Date of signature : 2017.9.6



## Informed Consent Signature Page

Research Title :

Effects of Intravitreal Ranibizumab for Macular Edema With Nonproliferative Diabetic retinopathy  
( NCT02834663 / CRFB002DKR03T )

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Signer's signature: \_\_\_\_\_

Date of signature : 2017. 9. 27

Signature by legal agent (if necessary): \_\_\_\_\_

Date of signature : \_\_\_\_\_

Witness signature (if necessary): \_\_\_\_\_

Date of signature : \_\_\_\_\_

We have read and explained the informed consent to the subject, and then answered all the questions he/she has raised. Him/herself has also already understood and agreed to participate in the scientific research.

Signatures of researchers : \_\_\_\_\_

Date of signature : 2017. 9. 27

## Informed Consent Signature Page

Research Title :

Effects of Intravitreal Ranibizumab for Macular Edema With Nonproliferative Diabetic retinopathy  
( NCT02834663 / CRFB002DKR03T )

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Signer's signature: \_\_\_\_\_  \_\_\_\_\_ Date of signature : 2017-12-12

Signature by legal agent (if necessary): \_\_\_\_\_ Date of signature : \_\_\_\_\_

Witness signature (if necessary): \_\_\_\_\_ Date of signature : \_\_\_\_\_

We have read and explained the informed consent to the subject, and then answered all the questions he/she has raised. Him/herself has also already understood and agreed to participate in the scientific research.

Signatures of researchers :  \_\_\_\_\_ Date of signature : 2017, 12.12

## Informed Consent Signature Page

Research Title :

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( NCT02834663 / CRFB002DKR03T )

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Signer's signature: \_\_\_\_\_

Date of signature : 2018, 1, 17

Signature by legal agent (if necessary): \_\_\_\_\_

Date of signature : \_\_\_\_\_

Witness signature (if necessary): \_\_\_\_\_

Date of signature : \_\_\_\_\_

We have read and explained the informed consent to the subject, and then answered all the questions he/she has raised. Him/herself has also already understood and agreed to participate in the scientific research.

Signatures of researchers : OF OVA

Date of signature : 2018, 1, 17

## Informed Consent Signature Page

Research Title :

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( NCT02834663 / CRFB002DKR03T )

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Signer's signature: \_\_\_\_\_ Date of signature : \_\_\_\_\_

Signature by legal agent (if necessary):  Date of signature : 2018.2.28

Witness signature (if necessary): \_\_\_\_\_ Date of signature : \_\_\_\_\_

We have read and explained the informed consent to the subject, and then answered all the questions he/she has raised. Him/herself has also already understood and agreed to participate in the scientific research.

Signatures of researchers :  Date of signature : 2018.2.28

## Informed Consent Signature Page


Research Title :

Effects of Intravitreal Ranibizumab for Macular Edema With Nonproliferative Diabetic retinopathy  
( NCT02834663 / CRFB002DKR03T )

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Signer's signature: \_\_\_\_\_ Date of signature : \_\_\_\_\_

Signature by legal agent (if necessary):  Date of signature : 2018.5.28

Witness signature (if necessary): \_\_\_\_\_ Date of signature : \_\_\_\_\_

We have read and explained the informed consent to the subject, and then answered all the questions he/she has raised. Him/herself has also already understood and agreed to participate in the scientific research.

Signatures of researchers :  Date of signature : 2018.5.28

## Informed Consent Signature Page

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Signer's signature: \_\_\_\_\_  \_\_\_\_\_ Date of signature : 2018. 8. 20

Signature by legal agent (if necessary): \_\_\_\_\_ Date of signature : \_\_\_\_\_

Witness signature (if necessary): \_\_\_\_\_ Date of signature : \_\_\_\_\_

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Signatures of researchers :  \_\_\_\_\_ Date of signature : 2018. 8. 20