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# Short Duration Hyperbaric Oxygen Therapy to Improve HbA1c, Leukocyte, and Serum Creatinine in Patient with Diabetic Foot Ulcer Wagner 3-4

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Denpasar, 10-04-2018

dr. Hendry Irawan

# INFORMED CONSENT
# AS A RESEARCH PARTICIPANT

We ask Mr / Mrs to participate in the research. The participation of this study is voluntary. Please read the explanation below and please ask if any questions / if there are things that are less clear.

| **SHORT DURATION HYPERBARIC OXYGEN THERAPY TO IMPROVE HBA1C, LEUKOCYTE, AND SERUM CREATININE IN PATIENT WITH DIABETIC FOOT ULCER WAGNER 3-4** | |
|---|---|
| **Primary researcher** | dr. Hendry Irawan |
| **Faculty/ University/ Department/ Affiliation** | Surgery Department, Faculty of Medicine, Udayana University, Sanglah General Hospital, Denpasar, Indonesia |
| **Other researcher** | dr. I Nyoman Semadi, Sp.B, Sp.BTKV<br>Prof. Dr. dr. I Gde Raka Widiana, Sp.PD-KGH |
| **Place of research** | RSUP Sanglah Denpasar |
| **Sponsorship/ Funding** | Self-financing |

Diabetes mellitus (DM) is a chronic disease that occurs when the pancreas does not produce enough insulin, or when the body can not use insulin effectively with elevated blood sugar levels that can cause damage to the heart, blood vessels, eyes, kidneys, and nerves. DM starts from asymptomatic to asymptomatic and if it continues to cause chronic complications in various organs.

One of the complications of type 2 DM is a foot injury that is difficult to heal (diabetic foot ulcers) and can result amputation. Because of the difficulty of wound healing, much research has been done in the field of diabetic foot wounds to obtain good techniques for healing. One of the therapeutic techniques is hyperbaric oxygen therapy.

Hyperbaric oxygen therapy is a 100% oxygen delivery with high pressure in hyperbaric chamber for 90 minutes per day, at least 10 days. Increased oxygen causes the death of bacteria so that the infection decreases, the loss of infection causes the process of inflammation decreased marked by decreased white blood cells / leukocytes in the blood. The function of renal organ protection gradually decreases in blood sugar is characterized by a decrease in serum creatinine levels in blood plasma. Decrease in blood sugar is characterized by a decrease in HbA1c levels in the blood.

This therapy will be carried out in the multiplace hyperbaric chamber of Sanglah Hospital Denpasar on weekdays, with the criteria of DM patients who have diabetic foot injuries aged over 18 years and participants not experiencing serious disorders such as heart failure, lung infection, pneumothorax, chronic lung disease, and stroke. The duration of each participant's study is 2 weeks.

The aim of this study was to compare diabetes therapy with and without hyperbaric oxygen therapy. The study participants will be grouped into 2, there are the control group (study participants performing conventional therapy) and the treatment group (study participants performing conventional therapy and hyperbaric oxygen therapy for 10 consecutive working days). In both groups blood analysis were performed.

**Benefits for study participants**

Participation in this study directly benefited the study participants, such as healing diabetic foot wounds faster, lower blood sugar levels, reduce the rate of bacterial infection, and protect the kidneys. This therapy can provide more information about the use of hyperbaric oxygen therapy in diabetic foot wounds.

**Discomfort and risk / loss that may be experienced by the study participants**

Patients may experience discomfort for fear of being in a closed space and the risk of temporary hearing loss. This risk is rare.

**Alternative action / treatment**

None.

**Compensation, Cost of Inspection / Measures and availability of medical treatment in case of undesirable outcomes**

There is no financial compensation for your participation in this research. Researchers bear the cost of inspection / action of hyperbaric oxygen therapy that will be done in this study. The medical procedure performed in this study is a low risk standard procedure.

**Confidentiality of Participant Data**

All existing data is stored by the researcher.

**Participation in this study is voluntary**

The participation of Mr / Ms in this study is voluntary. Mr / Mrs may refuse to answer questions raised on research or to terminate membership of any study without any sanction. The decision of Mr / Ms to quit as a research participant will not affect the quality and access / continuation of treatment to Sanglah Hospital.

**IF AGREE TO BE A RESEARCH PARTICIPANT**

f you agree to become a participant of this research, you are required to sign the Informed Consent Form as a Research Participant / Guardian after you are fully aware of the research. Mr / Ms will be given a copy of this signed agreement.

If during the study there are new developments that can influence the decision of Mr / Ms for continuation of membership in research, the researcher will convey this to Mr / Ms.

If any questions need to be submitted to the researcher, please contact dr. Hendry Irawan, 082125097786, hendry_irawan@rocketmail.com.

The signature of Mr / Ms below indicates that Mr / Mrs has read, has understood and has had the opportunity to ask the researcher about this research and **agree to be a research participant**.

**Research participant,**

*Signature and Full name*
*Date: / /*

**Wali,**

*Signature and Full name*
*Date: / /*
***Relationship with Research Participant:***

**Researcher,**

dr. Hendry Irawan

*Signature and Full name*

*Date: / /*

**RESEARCH FORM**

**SHORT DURATION HYPERBARIC OXYGEN THERAPY TO IMPROVE HBA1C, LEUKOCYTE, AND SERUM CREATININE IN PATIENT WITH DIABETIC FOOT ULCER WAGNER 3-4**

Name participant:

Sex: M / F Age: years

Home address: Phone:

No. Medical record: Ward:

Date of Hospital admission:

Date of Hospital discharge:

History of smoking: Yes / No

History of hypertension: Yes / No

Duration of DM: years

Duration of foot ulcer: weeks

**Physical examination**

DM DF Wagner: 3 / 4

Weight: kg

Height: cm

BMI: $kg/m^2$

| **Laboratory analysis** | ***pretest*** | ***posttest*** |
|---|---|---|
| HbA1c (%) | | |
| Hb (g/dL) | | |
| Leukocyte (sel/µL) | | |
| Creatinine (mg/dL) | | |
| Albumin (g/dL) | | |