

STUDY INFORMED CONSENT COVER PAGE

Official Title: Randomised Controlled Trial of Two Different Cumulative Dosages of Roaccutane for Cystic Acne

Short Title: Roaccutane 120 mg/kg vs 150 mg/kg for Cystic Acne

Principal Investigator: Prof. Dedee F. Murrell, St George Hospital, Kogarah NSW, Australia

Study Identifier (NCT Number): To be assigned by ClinicalTrials.gov upon registration

Date: 17 October 2000

The St George Hospital & Community Health Service

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Approval No: 00/102 Murrell

SOUTH EASTERN SYDNEY AREA HEALTH SERVICE ETHICS COMMITTEE SOUTHERN SECTION

SUBJECT INFORMATION AND CONSENT FORM

Title of Project: Cumulative Roaccutane dose and risk of acne recurrence.

Roaccutane is an effective therapy for moderate to severe acne. The medication is typically used in patients who have failed to respond to conventional therapies (i.e. oral antibiotics) or who exhibit acne scarring. Although the majority of patients treated with a course of Roaccutane will have complete clearing of their acne, a small but significant percentage of patients will develop a recurrence of acne over time and require additional therapy. We are performing a study to evaluate the treatment dose of Roaccutane that will limit recurrences of acne.

What does of the study involve?

The study will compare two different cumulative Roaccutane doses and assess the risk of acne recurrences after completion of treatment for at least one year. Approximately 100 patients will be enrolled in the study. Should you choose to participate, you will be randomized into one of two treatment groups. One group will receive a cumulative Roaccutane dose of 120mg/kg and the other group 150mg/kg. Both of these doses have been shown to result in complete clearing of acne in the majority of cases. You will take Roaccutane on a daily basis as prescribed by one of the study dermatologists until you reach the total cumulative dose (typically 4-8 months of treatment). Follow-up visits will be held every six to eight weeks while you are on Roaccutane, at which time you will be evaluated for therapeutic response and side-effects. Photographs will be taken at each visit to assist in monitoring response to treatment. Laboratory evaluations will be performed at each visit as necessary. After completion of treatment, follow-up visits will occur every three months for at least one year. During these visits, you will be evaluated for a recurrence of your acne.

Patients Signature: _____

Possible Benefits

Roaccutane is an extremely effective treatment for acne and is the only therapy available that can potentially cure acne. The majority of patients treated with a course of Roaccutane will experience complete clearing of their acne with prolonged remissions.

Possible Risks

Roaccutane has a well-established side effect profile. Some of the more common adverse effects include:

- Drying of the skin and mucosal surfaces
- Headaches
- Visual disturbances
- Bone stiffness or muscle aches
- An increased susceptibility to sunburn
- Hepatotoxicity. In most cases, liver enzymes return to normal levels by decreasing the dose of Roaccutane or discontinuing therapy
- Elevation of lipid levels (triglyceride and cholesterol)
- Diabetic patients may need more frequent monitoring of blood sugars as levels may become increased while on Roaccutane
- Risk of drug interactions if taking concurrent medications.

You will be provided with a patient information sheet that is supplied by the company that manufactures Roaccutane. This information sheet will review the potential adverse effects in more detail. Please feel free to address any concerns that you may have with one of the study physicians. Roaccutane is a safe therapy when used appropriately and in experienced hands.

What will I get out of the study?

Your acne should improve significantly after treatment. Your participation will also assist physicians to choose the most appropriate treatment doses of Roaccutane in the future to give the most benefits with the fewest adverse effects.

Alternatives to Participation

If you choose not to participate in this study, or if you choose to withdraw from the study, you may still receive treatment with a standard course of Roaccutane for management of your acne. Other treatment options include oral antibiotics, hormonal therapy, and topical therapies.

Confidentiality and Disclosure of Information

All data generated in the study will be kept confidential so that it will be impossible to identify any patients from the data collected in the trial. The data will be computerized to compile, validate, and report the data.

Patients Signature: _____

The study physician will also write a letter to your GP to tell him/her that you are taking part in a study. The confidentiality of your notes is assured and your name will not appear in any publications or reports.

Pregnancy

Pregnant or breast-feeding women are not permitted to take part in this study. Roaccutane is a known teratogen and can cause serious risks to a developing fetus. Furthermore, all women of childbearing potential must document a negative serum pregnancy test prior to initiating treatment with Roaccutane and at 2 month intervals throughout the course of treatment. Two effective forms of contraception (i.e. oral contraceptive pill and condoms) must be used for one month before and continued for one month following discontinuation of Roaccutane therapy. A pamphlet outlining contraceptive methods will be provided to you. Abstinence is not a recommended form of contraception and patients wishing to choose this method of contraception must sign a waiver acknowledging the risks involved.

Participation is voluntary

Your participation in this study is entirely voluntary: you are in no way obliged to participate and, if you do participate, you can withdraw at any time. Whatever your decision, please be assured that it will not affect your medical treatment or your relationship with medical staff. Termination of your participation in the trial may also occur if you experience a serious adverse event(s) or if the study is stopped by the company making Roaccutane or by the authorities approving the conduct of this trial.

Before deciding whether or not to take part in this study, you may wish to discuss the project with a relative or friend or your local health worker.

You will be informed in a timely manner if any new information becomes available which may influence your decision to remain in this study.

Further information

When you have read this information, Dr Murrell or Dr ^{Martin} Cummins will discuss it with you further and answer any questions you may have. Only sign the Consent Form once you have had a chance to ask your questions and have received satisfactory answers.

If you have questions at any time during the study, feel free to contact Dr Murrell or Dr Cummins at (02) 9350 2543. A copy of this information sheet will be made available for you to keep. or 0412 956 745

Patients Signature: _____

Complaints

Complaints may be directed to the Ethics Secretariat, South Eastern Sydney Area Health Service Research Ethics Committee (Southern Section), St George Hospital, Gray Street, Kogarah 2217. Telephone: 9350 2986 Fax: 9350 2988. Email: draker@sesahs.nsw.gov.au

Thank you for your interest in this study.

You will be given a copy of this form to keep.

Patient's signature: _____



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**SOUTH EASTERN SYDNEY AREA HEALTH SERVICE ETHICS
COMMITTEE SOUTHERN SECTION**

SUBJECT INFORMATION AND CONSENT FORM (continued)

(Title of Project: Cumulative Roaccutane dose and risk of acne recurrence.)

You are making a decision whether or not to participate. Your signature indicates that you have decided to participate having read the information provided above.

Signature of Subject

Signature of Witness

Please PRINT Name

Please Print Name

Date

Nature of Witness

Signature(s) of Investigator(s)

Please PRINT Name



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SUBJECT INFORMATION AND CONSENT FORM (continued)

(Title of Project: Cumulative Roaccutane dose and risk of acne recurrence.)

REVOCATION OF CONSENT

I hereby wish to WITHDRAW my consent to participate in the research proposal described above and understand that such withdrawal WILL NOT jeopardise any treatment or my relationship with the St George Hospital or my medical attendants.

Signature

Date

Please PRINT Name

The section for Revocation of Consent should be forwarded to Dr Dédée Murrell, Department of Dermatology, St George Hospital, Kogarah, NSW.