Government of South Australia
SA Health

Dr Charles Cock

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Dear Editor and Reviewers

World Journal of Gastroenterology

Re: 32029 Age-related Impairment of Esophagogastric Junction Relaxation and Bolus Flow Time

I hereby confirm that all subjects included in this study signed informed consent, which is kept on record in our unit.

I include the original (unsigned) consent form for your consideration.

Yours Faithfully

Dr Charles Cock, ***FRACP***
Director Investigation and Procedures
Repatriation General Hospital

REPATRIATION GENERAL HOSPITAL
INVESTIGATION & PROCEDURE UNIT

Participant Information Sheet

Study Title: Use of a novel technique to assess swallowing function in healthy older adults (Protocol no. 403/10)

Chief Investigator Details: Dr Charles Cock MBChB, MMed, MA, CMSA, FRACP
Senior Consultant, Investigation and Procedure Unit, Repatriation General Hospital

Invitation to participate: You are invited to participate in a research project conducted by Dr Charles Cock and Colleagues. You do not have to be involved and whether you wish to or not is entirely up to you. Whether you take part or not, your medical care/relationship with the Repatriation General Hospital will not be affected in any way. You may also withdraw from the project at any time.

Aims of the project: Difficulty swallowing is a common condition that negatively affects many patients. A new technique has been developed which provides a better assessment of swallowing function. This has the potential to significantly improve treatment options. Current information, however, is limited to patients with swallowing difficulties and data from healthy adults of different age groups are needed for comparison.

Summary of procedures: You would be required to attend the Investigation and Procedures Unit, Repatriation General Hospital, on a minimum of one occasion (potential second visit for a 12-month follow-up study). You will not be able to have anything to eat 3 hours before your appointment but you can still have water to drink up to an hour before the procedure. We will use local anaesthetic in one nostril, and pass a small catheter (3.2mm diameter) through the nose, down the back of the throat and into your oesophagus. This special device measures the muscular contractions of the gullet and the flow of liquids as you swallow. With the catheter in place, you will be asked to swallow small amounts (approx. 1 teaspoon) of liquid (slightly salty water) and semi-solid (jelly) once every 20 seconds, for a total of 20 swallows. You will then be asked to swallow 5 x 2ml liquid swallows in quick succession (2 seconds or less between each swallow). The catheter will then be re-positioned in the upper oesophagus / pharynx and the swallows will be repeated, as outlined above. The procedure will take approximately 45 minutes. The assembly will then be removed and you will be offered a light refreshment before leaving the laboratory.

You will then be invited to participate in a follow-up study in 12 months' time. This would involve you undergoing the same procedure as described above. If you agree, we will contact you within 12 months to organise your follow-up appointment. You are under no obligation to return for the follow-up visit, and retain your right to remove yourself from the study at any time.

Commitments: You will be asked to attend the Repatriation General Hospital on one occasion. The procedure will take approximately 45 minutes.

Benefits: You will not receive any direct benefit from participating in the study. You will be offered an honorarium of $50 (each visit) for your time and inconvenience spent in the laboratory. This project aims to further medical knowledge and may improve treatment of patients with swallowing difficulties in the future.

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REPATRIATION GENERAL HOSPITAL DAW PARK

REPATRIATION GENERAL HOSPITAL
INVESTIGATION & PROCEDURE UNIT

Consent to Participation in Research

I, ... request and give
(first or given names) *(last name)*

consent to my involvement in the research project: *Use of a novel technique to assess swallowing function in healthy older adults (Protocol no. 403/10)*

I acknowledge the nature, purpose and contemplated effects of the research project, especially as far as they affect me, have been fully explained to my satisfaction by:

.....
(first or given names) *(last name)*

and my consent is given voluntarily.

I acknowledge that the detail(s) of the following has/have been explained to me, including indications of risks; any discomfort involved; anticipation of length of time; and the frequency with which they will be performed:

1. Attending the Laboratory on one occasion for approximately 45 minutes
2. Insertion of a catheter through my nose (using local anaesthetic) and into my oesophagus, which will measure pressure and flow during 20 swallows of liquid or semi-solid (approx. 1 teaspoon each)
3. Re-positioning of catheter in upper oesophagus and swallows repeated as above

I have understood and am satisfied with the explanations that I have been given.

I have been provided with a written information sheet.

I understand that my involvement in this research project may not be of any direct benefit to me and that I may withdraw my consent at any stage without affecting my rights or the responsibilities of the researchers in any respect.

I declare that I am over the age of 18 years.

I acknowledge that I have been informed that should I receive an injury as a result of taking part in this study, I may need to start legal action to determine whether I should be paid.

Signature of Research Participant:..... Date: .....

I, ... have described to , ...

the research project and nature and effects of procedure(s) involved. In my opinion he/she understands the explanation and has freely given his/her consent.

Signature: ..... Date: .....

Status in Project: .....

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