

FACULTY OF MEDICINE AND HEALTH SCIENCES STELLENBOSCH UNIVERSITY

MEDIA STATEMENT

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Stellenbosch University awarded contract to direct large clinical study in trauma resuscitation

- Patient enrolment expected to commence by mid-2019 and conclude by 2021
- Ground-breaking clinical research that has the potential to change pre-hospital care of civilian and military trauma victims worldwide

Emergency medicine experts from Stellenbosch University (SU) are embarking on a large, multiinstitutional clinical trial in partnership with the United States Department of Defence, to evaluate the use of synthetic blood-products for the resuscitation of trauma victims before arrival at hospital.

The Division of Emergency Medicine at SU's Faculty of Medicine and Health Sciences will be the coordinating centre for the study, which includes 21 hospitals and 27 ambulance bases across South Africa. These include public and private academic institutions and healthcare facilities. For this study, SU is also partnering with the Universities of Cape Town (UCT), KwaZulu-Natal (UKZN), Witwatersrand (Wits) and Pretoria (UP), collectively representing the body of academic emergency medicine in South Africa.

The study will evaluate the use of the haemoglobin-based oxygen carrier Hemopure (HbO2 Therapeutics LLC) together with Bioplasma FDP (National Biologics Institute), a freeze-dried plasma, to resuscitate trauma victims prior to arrival at the hospital emergency centre. Haemoglobin is a naturally occurring protein responsible for transporting oxygen through the blood, while plasma is the colourless fluid part of the blood that contains proteins that make blood clot.

Trauma is the leading cause of death and disability among young adults, which is often due to severe blood loss. Bleeding following trauma causes 1.5 million deaths a year worldwide. South Africa has a high burden of trauma, especially amongst young adults. Improvements in survival and better clinical outcomes from trauma result from early diagnosis, rapid bleeding control, and the early deployment of ambulances to rapidly transport patients to advanced medical care.

Blood transfusions can be life-saving but are rarely available prior to hospital arrival. At least half of all trauma deaths occur prior to hospital arrival, therefore earlier and better pre-hospital care strategies can improve clinical outcomes. However, due to shortages of blood products and storage

and logistic challenges, the opportunities for pre-hospital staff to administer blood products remain very limited.

Hemopure and Bioplasma FDP have been used extensively in hospitals in South Africa for several years. Together, it provide both oxygen-carrying capacity and allow the patient's blood to clot. It does not have the logistic and storage challenges of fresh blood, and is ideal for pre-hospital use. South Africa is the only country in the world in which both these products are currently available and registered for clinical use.

"Patients that experience excessive bleeding before arriving at hospital have for many years been resuscitated with salt water. However, this solution cannot carry oxygen and can interrupt the natural clotting process of injured blood vessels," says Prof Lee Wallis, Head of SU's Division of Emergency Medicine. "Hemopure and Bioplasma FDP are specifically designed to restore the oxygen-carrying capacity and the clotting function of the patient's own circulating blood. This can be a lifesaving bridge to allow emergency personnel to get patients to a site where they can receive blood and surgery, and has the potential to make a major impact on patients who might have otherwise died," added Wallis.

In addition to trauma experts and academic institutions, multiple other governmental organisations in South Africa and the United States of America are contributing to this undertaking. The project also enjoys the support from the South African Military Health Services.

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