**Helsinki Committee**

**Request for Approval**

A: Personal Data

|  |  |
| --- | --- |
| **Date: 2019 October 5** | |
| **Name: Tarek Loubani** | **Residency: Canada** |
| **Institution: University of Western Ontario** | **Specialty: Emergency Medicine** |
| **Degree: Associate Professor, Medical Doctor** | **Place of work: London Health Sciences** |
| **Mobile:** | **Email: tarek@tarek.org** |

**B: Proposal Details**

**1. Title:**

Prospective clinical trial comparing effectiveness of 3D printed and injection molded open source tourniquet against premium commercial tourniquets.

**2. Objectives:**

1. To compare a 3D printed open source tourniquet against the premium brand Combat Application Tourniquet (CAT).

2. To compare an injection-molded open source tourniquet against the premium brand Combat Application Tourniquet (CAT).

3. To compare a 3D printed open source tourniquet to an injection-molded open source tourniquet.

**3. Methodology**

**3.1. Study design:**

Unblinded prospective randomized controlled trial

**3.2. Study population:**

All trauma patients with life threatening external bleeding that can be manged by tourniquet application by the main ambulance service providers (PRCS-MOH-PCD and MMS) during the study period.

**3.3. Expected date of data collection:**

Upon approval of ethics (expected before 2020 January 1) until 2021 December 31

3.4. Data collection:

|  |  |  |
| --- | --- | --- |
| **Questionnaire** | **Yes** | |
| **Blood testing** | **No** | |
| **Other tissues or specimen exam** | **No** | |
| **Are you giving drugs?** | **No** | |
| **Are you intending to perform surgical or physical procedures?** | **Yes** | |
| **If yes, describe: A tourniquet will be applied proximal to the area of injury causing exsanguination. The tourniquet will then be tightened according to internationally recognized procedures until bleeding is controlled on the patient.** | | |
| **Do you plan to get informed consent** | **No** |  |
| **If No, justify:**  **1. Administration of the tourniquet is a lifesaving procedure. Obtaining consent would delay care in a dangerous and life-threatening manner.**  **2. The 3D printed tourniquet is already in use in the field in Gaza today and has shown success so far.**  **3. The CAT is the current standard of care and would be used on patients in other countries.**  **4. The injection-molded tourniquet is based on the 3D printed tourniquet design and is expected to perform equivalently to the 3d printed tourniquet and the CAT.** | | |
| **If you have further details please add here:** | | |
| **All the given information are TRUE** | **Signature**  **Tarek Loubani** | |