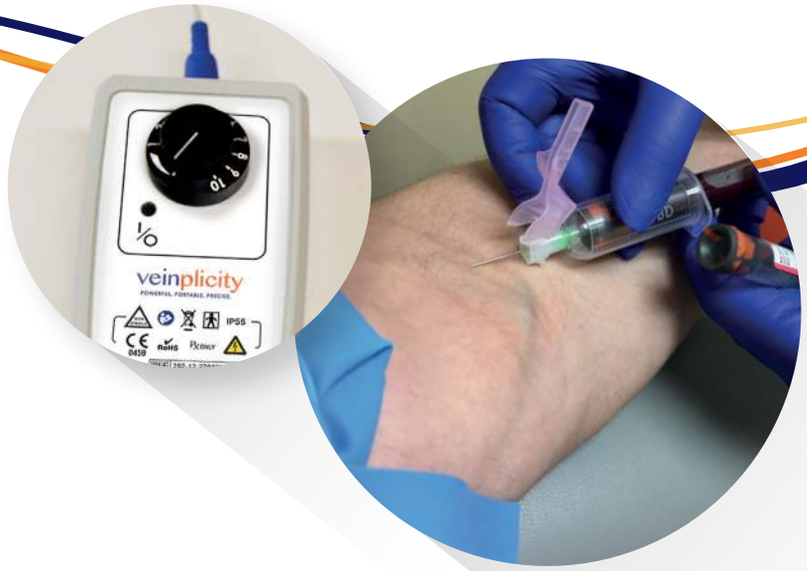
veinplicity
POWERFUL. PORTABLE. PRECISE.



Veinplicity™ **clinical studies**

An Acute GLP Safety Evaluation of the Vein Device in the Swine Model

The purpose of this study was to confirm that the Vein Device (now known as Veinplicity) did not induce any clinically relevant changes in clinical pathology.

The animal study was a control study with two animals. One animal received maximum stimulation for 10 minutes with the Vein Device and the other received no treatment and served as a control. Blood for clinical pathology was collected and analysed at baseline; 5, 10, 15, 30, 60, 90 and 120 minutes post treatment initiation.

No changes in blood chemistry between the control and treatment animal were observed. The tests undertaken were: CBC (RBC, Hb, Hemacrit, Platelet Count, WBCC, 5 part WBCD), Serum Chemistry (Urea Nitrogen, Creatinine, Total Protein, Albumin, AST, Bicarbonate, Glucose, Sodium, Potassium, Chloride, Calcium and Phosphorus), LDH and Lactic Acid.

The study successfully met all endpoints and no relevant changes to the blood chemistry were observed within in the animal model.

A Feasibility Study of the Veinplicity Venous Access Device

PROTOCOL 292-13-272472-01 FEBRUARY 2015

The purpose of this feasibility study was to assess the Veinplicity device as an adjunctive venepuncture tool in subjects with a history of difficult-to-access veins. The study collected information about the device, intravenous access, user/patient perceptions and device or procedural complications, as well as other adverse events.

Twenty patients who had a history of difficult venous access had electrical stimulation from the Veinplicity device. Following a positive reaction (a visible or palpable vein) the nurse proceeded to undertake conventional venous access, using an 18-gauge cannula. The study population age ranged from 22 to 66, with a mean age of 45.1 years. The patients' BMI ranged from 19.4 to 41.3 (mean 30.69 kg/m^2).
Note: Obesity deemed to be a BMI >30 kg/m^2.

Cannulation was achieved successfully in 70% of patients. Two subjects reported adverse events relating to the device, arthralgia and pain in extremity; both were resolved by the seven day follow-up.

This feasibility study confirmed the performance of Veinplicity as a useful tool for venous access when used in patients with a history of difficult-to-access veins.

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A prospective, single centre, randomised, cross-over clinical trial to assess the safety and effectiveness of the Veinplicity venous access device

PROTOCOL 292-13-280681-01 AUGUST 2015

The purpose of this study was to examine Veinplicity as an adjunctive IV cannulation tool in subjects with a history of difficult-to-access veins. The study was a prospective, single-centre, cross-over, randomised trial. A total of 200 patients were entered into the study. Each patient was deemed to be his or her own control. The study population age ranged from 18 to 77, with a mean age of 49.7 years. The patients' BMI ranged from 16.5 to 65.7 (mean 32.59 kg/m^2). Note: Obesity deemed to be a BMI >30 kg/m^2. The study required two visits seven days apart with a seven day follow-up. Patients were randomised into four groups.

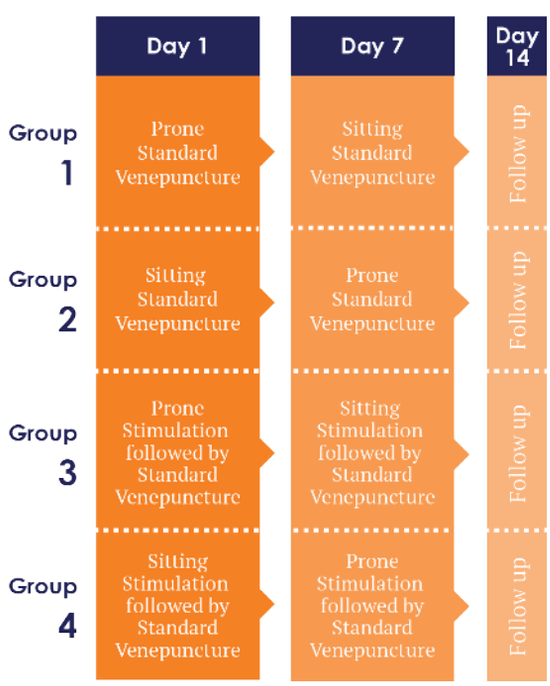
IV cannula placement was attempted using a standard 20-gauge cannula. The nurse was allowed to attempt venepuncture without tourniquet if he or she felt there was a reasonable chance of successfully placing the IV cannula (this occurred on 17 occasions in the stimulated arms, with 16 out of 17 first attempts being successful, compared to 1 attempt in the standard arm).

The study found that (when used with a tourniquet) there was no statistically significant difference in first attempt between stimulated and non-stimulated venepuncture. Stimulation led to a superior number of successful attempts following first failure.

No statistically significant difference in adverse events was observed between the enrolment groups, although in an adhoc analysis of the ITT population who reported a vasovagal response or side-effect, a trend towards a decrease in these events was observed in the stimulated-assisted treatment group.

A future study is warranted with patients who have a history of vasovagal responses to venepuncture to gain further data on this possible benefit. A further study is also warranted to compare first-attempt rates from stimulation alone to tourniquet alone.

200
patients with a history of **venous access difficulty** were randomised into **4 groups of 50**



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