Enabling self-treatment through a novel patient-driven facilitated subcutaneous immune globulin (fSCIg) administration

Contributing Authors: Ramona Fust, RN, BSN[1], Kristina Johansson, RN[2], Chatarina Soderman, RN[3], Andy Sealfon[4], Fred Ma, MD, PhD[5]

[1] University Hospital in Linköping, Department of Infectious Diseases, Linköping, Sweden, [2] Karolinska University Hospital, Immunodeficiency Unit, Solna, Sweden [3] (Former) RMS Medical Products, NY, USA, [4] CEO RMS Medical Products, NY, USA, [5] CMO RMS Medical Products, NY, USA

Background

To meet patient lifestyles or due to fear of needle-sticks, complications at infusion sites and adherence problems, fSCIg provides an opportunity to empower patients with an alternative. We present results from a novel self-treatment fSCIg using a consistent, accurate and constant pressure infusion system (CPIS) together with an adjustable flow rate controller (AFRC) calibrated to the viscosity of the drug. The CPIS has an intuitive and easy operation to provide accurate infusion flow rates. A high flow infusion set (24G) was used to allow up to 300 ml/hr flow rates to infusion sites.

Methods

fSCIg infusion data was recorded in a structured questionnaire at two departments specializing in treating primary immunodeficiency patients. Patients received education and training by an experienced nurse at the out-patient clinic.

Results

69 fSCIg infusions from 27 patients were recorded. Patients ranged in age from 25 to 81 years (mean 50 years). Males administered 54% and females 46% of the infusions. The nurse assessed when a comfort level of performing self-treatment was reached, which resulted in 93% of all infusions recorded. The average infusion time was 83 min. The AFRC used in the CPIS showed high quality performance, usability and safety with a total mean value score of 97 out of a maximum of 100 points.

Conclusion

A CPIS with a calibrated AFRC demonstrates to be convenient and empowers patients to successful self-treatment and home-therapy. It is easy to operate, safe and effectively delivers ultimate therapeutic outcome for patients' continual improvement of their well-being without triggering intolerable site reactions that patients sometimes have described.

References:

Guidance for Industry and Food and Drug Administration Staff Document "Applying Human Factors and Usability Engineering to Medical Devices", issued on: February 3, 2016.

Disclosure:

Authors of this presentation have the following to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation:

Ramona Fust, RN, BSN, University Hospital in Linköping, Department of Infectious Diseases;
Kristina Johansson, R.N., Karolinska University Hospital, Immunodeficiency Unit;
Chatarina Soderman, RN, (Former) RMS Medical Products;
Andy Sealfon, CEO, RMS Medical Products;
Fred Ma, MD, PhD, CMO RMS Medical Products

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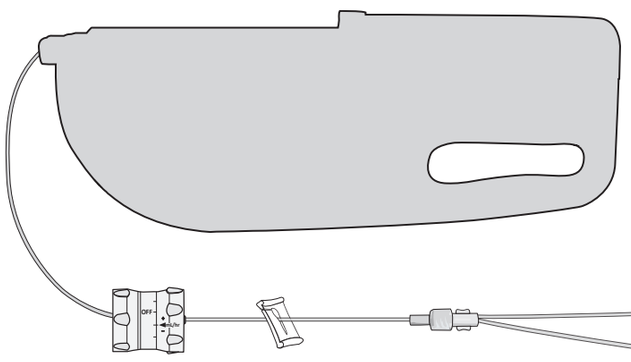
To request a copy of this study, please contact Dr. Fred Ma, RMS: **fma@rmsmedpro.com**

RMS MEDICAL PRODUCTS
RMS Medical Products
24 Carpenter Road
Chester, NY 10918, USA

Administration method



Constant Pressure Infusion System (CPIS)

Immediately responds to increasing pressure in site locations(s) by automatically slowing down. The built-in safety feature will maintain a safe pressure throughout the infusion, decreasing the possibility of site reactions.

24G Needle Set

24G delivers maximum flow of viscous drugs, up to 300ml/site/hr.

Adjustable Flow Rate Controller (AFRC)

Adjustable flow rate infusion set allows the patient to titrate administrations up or down for precise delivery of drug, over a specified period of time, per the instructions.

Training

Patients were trained at an out-patient clinic by an experienced nurse.

Data recorded

Infusion data was recorded in a 10 yes/no questionnaire at two PI departments.

27 patients recorded 69 fSCIg infusions

Study duration

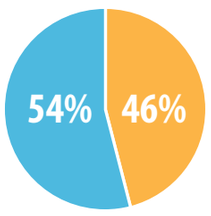
6 months

Age range

25 - 81 years

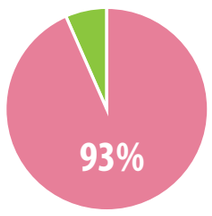
Infusion time

83 minute average



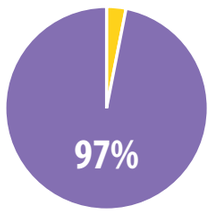
Nurse assessment

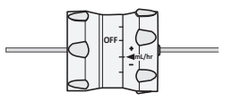
Comfort level of patients performing self-treatment was recorded.



System's overall score

- high quality performance
- easy to use
- safe





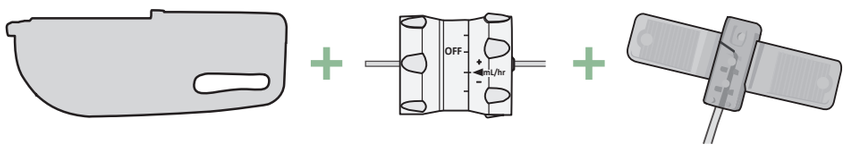
Flow rates used

21 30/60/120/240/300
2 30/120/240/300
4 no data

Questions which received 100% satisfaction rate

- Does the content in the Instructions For Use describe how to use the product well?
- Are instructions clear and easy to help you prime and set up 3CP?
- Is the needle set secured with Tegaderm?
- Were 10 minute intervals used as directed between infusion rates?

Conclusion



- Flow controller meets design and usability objectives
- Warrants effective mitigations for any human factor concerns
- Device is safe, easy to operate and performs accurately

System's benefits

- convenient
- empowering
- easy to operate
- fewer site reactions
- safe