Performance of Centargo: A Novel Piston-Based Injection System for High Throughput in CE CT * The PerCenT Study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON48114

Source
ToetsingOnline

Brief title
The PerCenT Study

Condition

- Other condition

Synonym
Adult patients referred for contrast-enhanced Computed Tomography, CT scan

Health condition

Adult patients referred for contrast-enhanced Computed Tomography

Research involving
Human

Sponsors and support

Primary sponsor: Bayer AG
Source(s) of monetary or material Support: Bayer AG

Intervention

Keyword: contrast enhanced CT, Performance outcome measures, Piston-Based Injection System, Pre CE Mark

Outcome measures

Primary outcome

The primary endpoint of the study is improved workflow efficiency via lower setup times and improved usability of Centargo vs Stellant MP. To measure time savings, setup time for the multi-patient set (MPDS for Stellant MP, Day Set for Centargo), change time for bottle/bag, patient setup time (SPDS for Stellant MP, Patient Line for Centargo), and teardown time for the MP set will be collected. The number of multi-patient sets used per day will also be recorded, allowing for calculation of the total amount of interaction time per day for each injector system.

No patient outcomes will be measured. Injection system Performance measures as described above.

Secondary outcome

1. Cost comparison: The number of multi-patient sets and single patient disposables used per day will be recorded. Multiplying by the cost per item will yield a total cost per day for an equal number of subjects.

2. Waste comparison: This will be calculated based on the number of

multi-patient sets used per day. Because of the additional flexibility of Centargo (ability to accommodate two compatible contrast agents, 24-hour vs. 12 hour in-use time), it is anticipated that fewer multi-patient sets will be required with Centargo. The reason for multi-patient set change will be recorded and summarized. The injection systems will automatically record unused contrast and saline in the multi-patient sets at time of teardown.

3. Injection system performance: Delivered flow rates and volumes, as well as generated pressure, will be automatically recorded for both systems. This will provide information as to whether the injection systems have sufficient achievable space and can maintain contrast temperature if necessary. Additionally, the injection system will automatically record any alerts such as communication loss, pressure limiting, air detection (Centargo only), or a full waste container (Centargo only).

4. Qualitative User Satisfaction: In order to compare the qualitative usability of Stellant MP and Centargo (specifically Centargo*s newly modernized user interface, automated filing and priming features, pre-assembled multi-patient set, etc.), radiographers will be surveyed on their satisfaction with the two systems.

5. System Reliability: For the second phase of the study, which is specific to Centargo only (no comparator), the overall reliability of the system

hardware and software will be measured

Study description

Background summary

The number of contrast-enhanced CT examinations is increasing all over the world each year. Reasons are easy access, short time to conduct a scan, and robustness and reproducibility of the examination. Due to the development of the scanner technology and the availability of Multislice/Multidetector CT, the time to conduct the scan itself has become shorter and can be less than one minute depending on the CT system used.

Power injection systems used for contrast-enhanced CT are well-understood technology with consistent technical capabilities, including ranges of flow rates, volumes, and pressures. Most common are syringe-based systems, where empty, disposable syringes are filled from contrast media (CM) bottles and saline bags. Tubing sets are then used to connect the syringes to the patient*s cannula/catheter in order to deliver the fluid. The injection system pushes a piston forward through each syringe, generating sufficient pressure to administer the programmed injection protocol, which is determined based on a variety of patient and procedure specific factors. The commercially available Stellant CT Injection System, which has been on the market for approximately 15 years, is an example of a syringe-based system and will be used as the comparator device in this study.

While performance of such devices is well-accepted, there are limitations from an efficiency perspective. The time to prepare the contrast media injection often takes longer than the image acquisition itself. There are *syringeless* systems that instead utilize peristaltic pumps to deliver the fluid, which have been shown to shorten setup and changeover time, but the performance is not necessarily comparable to a piston-based system. Maximum pressures can be lower, leading to smaller achievable space, and the pulsatility of the flow is higher.

The Centargo CT Injection System has been designed to maintain the advantages of a piston-based system but with the highest possible efficiency, allowing the radiographer to spend less time handling the injector and disposables and more time focusing on the patient. This is accomplished with the new disposable design, which comprises a 24 hour Day Set and a single-use Patient Line. The Day Set has 3 fluid reservoirs, with 3 corresponding inlet lines (2 for contrast media and 1 for saline), a manifold, and an outlet line. Instead of manually assembling the disposables as with Stellant MP (loading syringes onto the injector, removing dust caps, connecting transfer sets and connector

tubing), Centargo*s Day Set is fully pre-assembled in the package. Reduction in handling is considered an improvement in hygiene, reducing the risk of contamination of the fluid path. The patient line, which has dual check valves to prevent backflow for both Centargo and Stellant MP, has been updated to a single-click, one-handed insertion for Centargo. The patient end of the patient line remains connected to the injector until it is time to connect to the patient.

Other improvements with Centargo compared to Stellant include features to help prevent air injection and extravasation. Vascular air embolism is a known risk during a contrast-enhanced CT scan. For systems where fluid path is visible, it is up to the user to fill, prime appropriately, and check for air. Other systems, such as those with peristaltic pumps, have inlet and outlet air detectors. Detected air will lead to an interrupted injection and a potential repeat of the procedure (including exposure to additional radiation). Centargo has therefore taken this concern into account in the design. Similar to the peristaltic pumps, it uses inlet air detectors to prevent filling the Day Set from an empty bottle, and an outlet air detector will stop an in-progress injection if it detectors air. However, two other features help to reduce the risk of an interrupted injection. Air is automatically removed from the Day Set during filling (using a *vacuum cleaning* procedure), and the differences in compressibility between fluid and air are used to detect if any air remains in the reservoir. The Patient Line is also automatically primed as soon as it is inserted into the injector, eliminating the chance that the radiographer inadvertently connects an unprimed line to the patient.

For extravasation, the risk is largely related to catheter placement and patient characteristics and is unrelated to the injector itself. However, supporting features can aid the radiographer in detecting and preventing contrast media extravasations. Centargo, unlike Stellant, has a display in the scan room, so the radiographer can monitor the injection site while simultaneously viewing the pressure graph. It also allows for live adjustment of the flow rate up and down during the saline test injection.

Overall, with Centargo, the expected fluid delivery performance is comparable to other state of the art injection systems, but it also brings improvements in efficiency and opportunity for greater patient safety.

Study objective

The aim of the study is to compare an investigational injection system (Centargo) to the currently available Stellant CT injection system (with Multipatient disposable kit), in terms of efficiency, cost, performance, and user satisfaction (phase 1). It is also testing the overall reliability of the new injection system (phase 2).

Study design

This is a randomized multi-center, multi-country prospective clinical study. Patient population will be adults (* 18 years) already referred for Contrast Enhanced CT.

The centers* normally defined contrast injection and scan protocols will be used, with the only difference being injector group * Injector A (Centargo) vs. Injector B (Stellant MP). Because of the difference in equipment, it will be clear to which group the subject belongs; therefore it is not possible for the study to be blinded. No additional injections or scans beyond usual clinical practice will be performed. Patient participation is only for the time period of the procedure; the study does not require follow-up measurements or patient monitoring. The enrollment duration of the study at each center will be approximately 5 months, with a minimum of 100 subjects per group in the first phase of the study (see sample size rationale).

For each of the endpoints, data in the eCRF will be used to generate metrics comparing the two injection systems. Touch time is measured by subtracting start time from end time for each MP set setup, patient changeover, and MP set teardown. This will be summed over the course of a 24 hour period for each injection system and averaged over the length of the study.

Based on the number of MP sets, single patient disposables, and spikes consumed per day, the total waste will be calculated by volume and by weight, including packaging. Contrast waste will be measured by the residual contrast in the system at the end of the day (as recorded by the injection system) and averaged over the length of the study.
Similarly, each of the disposables has an associated cost, which will be multiplied by the number of each consumed. This will be divided by the total number of subjects to obtain a per-patient cost.

For the second phase of the study, testing hardware and software reliability, no comparator is required. Centargo will be used to perform the power injection for study subjects. Any error requiring a reboot of the system to continue will be recorded. Assuming a failure rate of 0.1%, approximately 2000 subjects total are required (see sample size justification); 100 from phase 1 of the study and an additional 1900 from this second phase.

Study burden and risks

Known potential risks:
Potential risks of the investigational device are consistent with those of any commercially available CT power injection system, which are primarily venous air injection, extravasation, repeat of exam, and infection due to contamination. Based on verification testing of the requirements for injector

performance and safety, there should be no additional risk to the patient with use of the investigational device. Testing has been performed to establish volume and flow rate accuracy, pressure behavior, electrical safety, and compliance other relevant standards. Any requirements not yet tested have been assessed with regards to potential patient risk. Detailed risk assessments are included in the Investigator Brochure. Additionally, onsite training will be provided to all study sites on the use of the new injection system to ensure radiographer understanding of labeling and workflow.

Known potential benefits:
Potential benefit to the study population would be increased safety due to new features available on the injector, such as air detection, automatic priming, and minimization of handling. While currently marketed power injectors have excellent safety profiles and are considered well-established, low-risk devices, the safe use of the device relies on operator expertise, vigilance and careful handling. Diligence in checking for air, using aseptic technique, assembling disposables correctly, and setting up the injector are all required. Centargo provides the opportunity to automate many of those manual steps. For example, the disposable kit is pre-assembled, does not require removal of multiple dustcaps and attaching individual tubing sets in the correct order. The patient line is automatically primed. The number of touch points and handling is reduced. Ultimately, the potential time and cost savings in the design of this device could benefit society as a whole, increasing the accessibility of CT by reducing the time required for preparation of contrast injections and decreasing costs.

Risk/benefit analysis:
Based on verification testing of the requirements for injector performance and safety, the risk to the patient with the investigational device should be no different from the control arm. The study population is subjects already referred for contrast-enhanced CT. Contrast injection protocols, scanner settings, and safety precautions in the case of an adverse event are according to the site*s typical practice, based on the indication for which imaging is being performed and any patient-specific needs, and will not be affected based upon which group a patient is randomized.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Adult subjects (* 18 years) referred for contrast-enhanced Computed Tomography
- Adult subjects capable of providing informed consent.

Exclusion criteria

- Pregnant and lactating women
- Children (< 18 years)
- Subjects with known hypersensitivity to iodinated contrast media
- Subjects with unacceptable renal function per local guidelines

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-12-2019
Enrollment:	525
Type:	Actual

Medical products/devices used

Generic name:	the MEDRAD Centargo CT Injection System
Registration:	No

Ethics review

Approved WMO

Date:	30-10-2019
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT03875469
CCMO	NL67971.068.19