Anaesthesia

An Open Label, Randomised Controlled trial of the effectiveness of Thermarmour vs Forced Air Warming in restoring normothermia in the Post Anaesthetic Care Unit

--Manuscript Draft--

Manuscript Number:	ANAE.2019.00060
Full Title:	An Open Label, Randomised Controlled trial of the effectiveness of Thermarmour vs Forced Air Warming in restoring normothermia in the Post Anaesthetic Care Unit
Short Title:	Thermarmour® for post-operative warming.
Article Type:	Original Article
Keywords:	Post-Operative Hypothermia; Forced Air Warming; Passive Warming
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Abstract:	Hypothermia is a common problem in Post Anaesthetic Care Units and can have significant effects on patients' post-operative morbidity. Numerous approaches and devices for warming patients in the post-operative period are available and have varying degrees of effectiveness. We conducted an open label, non-inferiority randomized controlled trial on a new device (Thermarmour®), comparing it against Forced Air Warming. Patients who had undergone elective surgery and were hypothermic (35.0°C – 35.9°C) on admission to the Post Anaesthetic Care Unit, were randomly allocated to be warmed by either the Thermarmour® blanket or Force Air Warming during their stay. We assessed patient's core temperature every 10 minutes from the start of warming, using Zero Heat Flux thermometry. We randomised 129 patients in a single UK centre (Thermarmour®, n=65 (50.3%) and Forced Air Warming, n= 64 (49.7%)). The predefined non-inferiority margin was a mean difference in temperature of 0.3°C between the groups at 60 minutes. Patients warmed with Thermarmour® were just 0.04°C (95% CI: -0.206,0.286, p=0.748) cooler than those warmed with Forced Air Warming, when adjusted for patient's temperature on arrival to the Post Anaesthetic Care Unit. Demonstrating in the context of this study Thermarmour® was non-inferior to Forced Air Warming. Additionally, there was also no difference between the groups for any associated post-operative consequences of warming (Shivering, Hypotension, Arrhythmias or Surgical Site infections).
Additional Information:	

Question	Response
Was written informed consent obtained for the study (and not just for anaesthesia/surgery, etc.) from all participants (including where skills are assessed in manikin studies), as detailed in the Instructions for Authors?	Yes, I/we confirm all the above
Research Ethics Committee approval for the study has been obtained.	Yes, I/we confirm the above
Name of Research Ethics Committee as follow-up to "Research Ethics Committee approval for the study has Been obtained	National Research and Ethics Service Leeds West Ethics Committee
Date approval granted as follow-up to Research Ethics Committee approval for the study has been obtained."	25/8/16
Please confirm if any of the authors have competing interests data (e.g. personal, financial or academic). Please refer to the form at http://www.icmje.org/coi_disclosure.pdf for examples of potential competing interests (though we do not require you to complete that form).	The authors do not have any competing interests.
Is your manuscript a Clinical Trial?	Yes
Please confirm that your trial has been registered in a public trial registry by providing the name of the registry and the unique registration no./code. as follow-up to "Is your manuscript aClinical Trial?"	ISRCTN 11563874

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Dear Editors

RE: An Open label, Randomised Controlled trial on the effectiveness of Thermarmour vs Forced Air Warming in restoring normothermia in the Post Anaesthetic Care Unit.

Please accept for consideration the above manuscript. We are happy for it to be considered as either a standalone submission or in regard to your recent call for submissions for a Special Issue on Peri-operative care planned for January 2020.

Yours sincerely

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Original Article

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An Open label, Randomised Controlled trial on the effectiveness of Thermarmour vs Forced Air Warming in restoring normothermia in the Post Anaesthetic Care Unit.

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Summary

Hypothermia is a common problem in Post Anaesthetic Care Units and can have significant effects on patients' post-operative morbidity. Numerous approaches and devices for warming patients in the post-operative period are available and have varying degrees of effectiveness. We conducted an open label, non-inferiority randomized controlled trial on a new device (Thermarmour®), comparing it against Forced Air Warming. Patients who had undergone elective surgery and were hypothermic (35.0°C – 35.9°C) on admission to the Post Anaesthetic Care Unit, were randomly allocated to be warmed by either the Thermarmour® blanket or Force Air Warming during their stay. We assessed patient's core temperature every 10 minutes from the start of warming, using Zero Heat Flux thermometry. We randomised 129 patients in a single UK centre (Thermarmour®, n=65 (50.3%) and Forced Air Warming, n= 64 (49.7%)). The predefined non- inferiority margin was a mean difference in temperature of 0.3°C between the groups at 60 minutes.

Patients warmed with the Thermarmour® were just 0.04°C (95% CI: -0.206,0.286, p=0.748) cooler than those warmed with Forced Air Warming, when adjusted for patient's temperature on arrival to the Post Anaesthetic Care Unit. Demonstrating in the context of this study the Thermarmour® was non-inferior to Forced Air Warming. Additionally, there was also no difference between the groups for any associated post-operative consequences of warming (Shivering, Hypotension, Arrhythmias or Surgical Site infections).

Inadvertent peri-operative hypothermia (core temperature below 36°C) remains a common occurrence in clinical practice [1,2]. With guidance recommending targeting a normal temperature range of between 36.5°C and 37.5°C for adult patients, except where clinically appropriate [1].

The risk of developing inadvertent peri-operative hypothermia varies widely but has been found to be as high as 73.5% in a cohort of Orthopaedic patients. [3-5]. It is precipitated by exposure of the skin and internal organs, ambient use of fluids and gases combined with the use of sedatives and anaesthetic agents inhibiting the physiological response to cold [6]. Those most susceptible include the elderly, patients with cancer and other chronic conditions, burn victims and patients with thyroid dysfunction [7].
The sequelae of peri-operative hypothermia can result in an increased morbidity, including cardiac complications, higher blood transfusion rates and delaying of wound healing leading to increased risk of surgical site infections [8-12].
Whilst avoidance of hypothermia is desirable it is often unavoidable. The institution of techniques to rewarm the patient promptly are essential to minimize potential complications, whilst ensuring interventions are well tolerated and effective.

Two different approaches to rewarming exist. Active warming; comprising the application of an external heat source i.e. Forced air warming and underbody resistive heating. Alternatively, passive rewarming consists of thermal insulation whereby the heat generated from the patient is conserved to enable rewarming to occur. i.e. reflective blankets.
Currently two Cochrane systematic reviews found no clear evidence of the warming effects of thermal insulation on core temperature during surgery or in the post-operative period resulting in advocating the use of Forced Air Warming [6,7].

One new passive warming device is the Thermarmour® thermal insulation blanket (Thermarmour, Kingston Upon Hull, UK) (Figure 1). This is a Class I medical device which under laboratory condition has demonstrated significant positive effect in respect of heat absorption, heat insulation and heat retention. There is currently no data on the effectiveness of the Thermarmour® in a clinical environment or comparison against other warming devices.

Figure 1 Thermarmour® blanket.

In the presence of a paucity of evidence of the Thermarmour's® clinical performance, our assessment of its predicted performance is based on the balance of previous studies comparing Forced Air Warming with passive warming devices and laboratory data supplied by the manufacturer [13-17]. As a result, we

hypothesise that there will be no clinically important difference between patient's temperatures at 60 minutes between patients receiving either Thermarmour® and Forced Air Warming.

Methods

We conducted a single centre, parallel design, stratified, open label, non-inferiority, randomised controlled trial. The protocol was reviewed by the National Research and Ethics Service, Leeds West committee (16/YH/0097) and registered on the ISCRTN database (ISRCTN11563874). In addition patient and public review of the protocol was undertaken by the Trans Humber consumer research panel.

The study was performed at Castle Hill Hospital, East Yorkshire, United Kingdom between December 2016 and October 2018. Adult patients (≥16 years) planned for major (>90 minutes) surgery were screened from elective theatre lists, initially from 8 Orthopaedic and latterly 3 Cardiothoracic surgeons. Patients were excluded if they were unable to provide informed consent, had known thyroid dysfunction, already participating in a conflicting research study and unable to understand English language.
Post-surgery, immediately on admission to a Post Anaesthetic Care Unit (PACU) a non-invasive Zero Heat Flux (ZHF) temperature sensor (SpotOn™, 3M, Bracknell, UK) was used to measure the patients' temperature (after a period of sensor stabilisation), with placement on the patient's lateral forehead. The patient's corresponding tympanic temperature (Genius 3, Cardinal Health, Dublin) was also taken as part of standard care.
Patients were randomised to receive either a warmed Thermarmour® blanket or a Forced Air Warming blanket if their temperature was between 35.0°C and 35.9°C. Patients outside of this temperature range were managed as per normal local practice and not included in the study.
Randomisation occurred on a 1:1 basis, using permuted blocks of 4, 6 and 8 with stratification for age (16 to 64 years and ≥65 years) and anaesthesia type (General and Spinal ± sedation) via a web-based generation software (Sealed Envelope™, London, UK).

Post randomisation, patients in the intervention group received an Thermarmour® blanket directly to the skin that had been warmed in a blanket warmer (Kingfisher, LTE Scientific, Oldham) set at 50°C, this was then covered with a single cotton sheet.

Patients in the control arm were warmed with either a Warm Touch WT 6000 or Warm Touch 5300 warming Unit (Covidien, Minneapolis) with a Warm Touch Full body warming blanket (Covidien, Minneapolis) and covered with a single cotton sheet.

Patients then had their temperature recorded every 10 minutes with the ZHF thermometry and tympanic probe up to and including discharge from PACU. Shivering, clinically significant hypotension and bradycardia, new arrhythmias and bleeding were identified and recorded as adverse events.

Ambient PACU temperature was recorded for the duration of the PACU stay for all randomised patients using a calibrated LogTag® TRID30-7 (LogTag, Auckland, New Zealand). All temperature measurement devices were regularly maintained and calibrated throughout the course of the study in line with existing organisational procedures.

At discharge from PACU to ward based care all subsequent treatments were at the discretion of the ward-based team. Patients were followed up until 7 days post-surgery or discharge from hospital; whichever occured first.

The primary objective of this study was to determine whether Thermarmour® was non inferior to Forced Air Warming in warming hypothermic patients. The primary outcome measure was mean temperature difference at 60 minutes post PACU admission. Secondary outcomes included PACU and hospital length of stay and the prevalence of all the adverse events including the severity of any post-operative shivering, which was graded 0-4. [18]

There are limited contemporaneous studies exploring Thermal insulation blankets against a Forced Air Warming device. In calculating the sample size, we used local unpublished temperature data indicating a standard deviation of 0.5, a non-inferiority limit of 0.3°C was set based on what was deemed to be clinically relevant. On this basis, 102 patients (51 per group) were required to be 90% sure that the lower limit of a one-sided fell within 95% confidence interval. In addition, we accounted for a potential 25% drop out of randomised patients who fail to reach the 60 minutes primary outcome point in PACU due to; return to theatre, subsequent admission to critical care, refusal to use the blanket or withdrawal of consent. In total we aimed to randomise 128 patients into the study.

For the primary outcome, temperature at 60 minutes post PACU admission, ANCOVA, adjusting for patient's temperature on arrival to PACU, was used to compare Thermarmour® with Forced Air Warming. Chi- squared tests were used to compare the categorical data between groups for the adverse events. A p-value
<0.05 was used to indicate statistical significance. Statistical analyses were performed using SPSS (Version 22, IBM, Portsmouth, UK).

Results

Five hundred and three patients were assessed for suitability for the study from which 276 consented to participate (see Figure 2),

Figure 2 CONSORT diagram of patient recruitment.

One Hundred and Twenty-Nine patients were randomized between the two groups; however, one patient was excluded from analysis due to the retrospective identification of pre-existing thyroid dysfunction. The split between surgical specialties was 96% (n=123) Orthopaedic and 4% (n= 5) Cardiothoracic. The patients' baseline characteristics are displayed in Table 1.

Table 1 Characteristics and intraoperative data of patients receiving Thermarmour® or Forced Air Warming. Values are mean (SD) or number (proportion).

	Thermarmour® (n = 64)	**Forced Air Warming** (n = 64)
Age; (years)	62.6 (14.3)	63.3 (14.2)
Sex; Male	38 (59%)	28 (44%)
Body Surface Area; (m^2)	1.97 (0.24)	1.96 (0.21)
ASA Physical Status		
I	14 (22%)	12 (19%)
II	33 (52%)	33 (51%)
III	16 (25%)	19 (30%)
Missing	1 (1%)	
General Anaesthesia (Yes)	35 (55%)	34(53%)
Spinal (Yes)	31 (48%)	32 (50%)
Vasopressors (Yes)	22(34%)	31(48%)
Ambient Temperature on PACU Arrival (°C)	23.7 (1.4)	23.6 (1.3)
First Spot On® Temperature (°C)	35.4 (0.3)	35.5 (0.3)
First Tympanic Temperature (°C)	35.5 (0.6)	35.5 (0.5)
Surgery Length (mins)	112.9 (68.0)	119.7 (56.7)
Anaesthesia Length (mins)	150.4 (77.7)	163.8 (66.7)

Orthopaedic Surgery	62 (97%)	61 (95%)
Cardiothoracic Surgery	2 (3%)	3 (5%)

Table 2 shows the temperature at each time point. At 60 minutes post warming device placement the mean temperature difference between Thermarmour® (n=30) with Forced Air Warming (n=32), when adjusted for patients temperature on arrival to PACU there was no statistical difference (p=0.748) between the mean difference of 0.040°C (95% CI: -0.206,0.286). Accordingly demonstrating that the Thermarmour® was non-inferior to forced air warming in this context.

In view of the low numbers of patients reaching 60 minutes of device usage, for patients who reached the 40 minutes of device usage (Thermarmour® (n=51) with Forced Air Warming (n=56)). These findings also show non inferiority with a mean difference was 0.045°C (95% CI -0.114, 0.204) (p=0.574) (Figure 3).

Figure 3 Mean Temperature (°C) differences at 40 and 60 minutes. Values are means with error bars for two-sided 95% Confidence Intervals. The non-inferiority margin is represented by a solid line set at 0.3°C.

Table 2 Mean Temperature at 10-minute intervals from device placement. Values are Mean (SD) and number

	Thermarmour	Forced Air Warming	ANCOVA, p-value
	Mean (SD), n	Mean (SD), n	
First Spot On Temperature (°C)	35.4 (0.3), 64	35.5 (0.3), 64	-
Temperature at 10 minutes (°C)	35.9 (0.4), 63	35.8 (0.4), 64	0.18
Temperature at 20 minutes (°C)	35.9 (0.4), 61	35.9 (0.4), 64	0.34
Temperature at 30 minutes (°C)	36.0 (0.4), 58	36.0 (0.5). 62	0.76
Temperature at 40 minutes (°C)	36.0 (0.5), 51	36.1 (0.4), 56	0.57
Temperature at 50 minutes (°C)	36.1 (0.5), 40	36.2 (0.5), 40	0.32
Temperature at 60 minutes (°C)	36.2 (0.6), 30	36.3 (0.5), 32	0.75

Regarding the safety aspects of the devices during patients' PACU stay there was a low instance of issues observed, with post-operative shivering the most common. There was no statistical difference between groups noted in any of the adverse event. (Table 3)

Table 3 Post-operative Adverse events in between Thermarmour® and Forced Air Warming patients (0.5 level of significance)

	Thermarmour	Forced Air Warming	p-value
Arrhythmia	1	0	0.32
Hypotension	1	2	0.56
Shivering	6	4	0.51
Surgical Site Infections	0	0	-

Patient stay data (Table 4) demonstrates a statistically shorter length of PACU stay for those patients who received Thermarmour® post operatively 67.3 mins (22:59) vs 80.2 (44:36). This did not translate to a shorter post-surgery length of hospital stay.

Table 4 Length of Stay for patient receiving Thermarmour® and Forced Air Warming. Values are mean (SD)

	Thermarmour	Forced Air Warming	p-value
PACU LOS (mins)	67.3 (22.6)	80.2 (44.4)	0.05
Post-Surgery Length of Stay (days)	3.1 (2.6)	3.3 (2.4)	0.64

The application of the warming device was slower in the FAW groups. Table 4 shows the time taken to place the device was significantly longer overall and from the point at which the baseline Spot On® temperature demonstrated hypothermia.

Table 5 Time taken to place warming devices for patient receiving Thermarmour® and Forced Air Warming. Values are mean (SD) minutes.

	Thermarmour	Forced Air Warming	p-value
PACU Admission to Spot On® Reading	5:28 (2:02)	06:26 (3:42)	0.71
PACU Admission to device placement	7:16 (2:36)	10:16 (4:04)	<0.001
Spot On® Reading to Device Placement	1:48 (1:33)	3:50 (2:18)	<0.001

Discussion

This study represents the first direct comparison of the Thermarmour products in a randomized controlled trial against any other warming device. The study is unique in that it compares a new passive warming blanket with the current advocated “gold standard” treatment for post-operative hypothermia [3].

For the primary outcome, the predefined non inferiority criteria of a temperature difference of less than 0.3°C at 60 minutes was observed. However, due to the small number of patients who had evaluable data at the 60 minutes timepoint we repeated the analysis for those who received 40 minutes of warming. It was also evident that non inferiority of Thermarmour® was established at this timepoint. We believe this demonstrates in the context of this study the efficacy of Thermarmour® in post-operative warming. These results are consistent with historic data using this outcome measure which also showed minimal impact of

FAW after 60 minutes of warming [13,14]. In the absence of Core Outcome set for patient, the use of this measure as a primary outcome may be flawed and alternative measures such as time to normothermia may provide more patient focused indicators of efficacy.

Whilst this study was not powered to identify any changes between the groups with regards to the post-operative adverse event; it is reassuring to see comparable incidence in this study. Of note is the incidence of surgical site infections (SSI), we used a pragmatic definition to determine the presence of SSI; "any non-prophylactic antibiotic use for suspected wound infection prior to hospital discharge". In both arms there were no surgical site infections during the initial hospital stay. Data for England identifies around a 0.6% incidence of SSI for comparable orthopaedic procedures to those undertaken in this study, with a median onset date of around 17-20 days [19]. In our study the intra-operative warming methods were not protocolized. With mixed evidence on the use and impact of FAW during surgery, the decision for its use was at the discretion of the surgeon and anaesthetist. The absence of SSI infections in the study is promising, in the presence of observed intra-operative Forced Air Warming use. However, patient's mean length of stay in this study was much shorter than the observed median days for onset of SSI in England.

The prevalence of postoperative hypothermia in this study was 62% which corresponds well with previous data [3-5]. Highlighting that despite recent efforts and techniques for pre and intraoperative warming temperature management in the post-operative phase remains as important. In view of current guidance for managing inadvertent perioperative hypothermia and the lack of clinical data on the efficacy of the Thermarmour® this study focuses on a narrow but clinically relevant temperature window (35.0 - 35.9°C). Accordingly, these data only reflect patients in the post-operative period, and it is unknown how the device would perform on patients presenting with temperatures outside this range.

NICE guidance recommends direct measurement of temperature in the perioperative phase, we took a pragmatic approach and ZHF was used to measure the primary outcome data. Whilst not widely adopted in the UK the use of the 3m Spot On/Bair Hugger probes, ZHF thermometry was based on a growing body of evidence describing increased accuracy and reduced variability, compared with other means of thermometry, whilst also being an acceptable and risk-free approach in awake patients [20-29]. We found close agreement between the mean first Spot On temperature and tympanic measurements but a higher degree of variation in the tympanic measurements. The possibility of a larger variance between the two thermometry methods is possible through different temperature ranges and the influence of the thermometry equipment should not be underestimated.

There are several limitations to this study; firstly, the nature of the interventions resulted in the inability to blind PACU staff to the randomization, for this reason we are unable unequivocally determine that specific outcomes have not been influenced by bias such as earlier discharge of patients. Secondly, we observed a statistically significant longer PACU length of stay for the FAW group; this may have been due to the

extended time taken to remove the warming equipment, however this it is unlikely to explain the entire delay. Likewise, the steeper warming trajectory of the Thermarmour® group may have readied the PACU nurse for the potential discharge.

Finally, it did take longer to start the FAW than the Thermarmour® on the patients. It is conceivable that this delay to setup the FAW was exclusively related to the practicality of delivering FAW i.e. locating a device, accessing a suitable power source and connecting hoses to blankets rather than any deliberate delay to start therapy. The impact of this real-world delay of instigating FAW is unclear in this study but may have resulted in underperformance of the FAW.

In summary when evaluating against mean patient temperature at 40 and 60 minutes this study demonstrates the Thermarmour non-inferiority to forced air warming in the post-operative phase in conditions described here. Alongside this during the patients' PACU stay the adverse event rates were low and were statistically not significantly different; demonstrating the clinical utility of the Thermarmour® in the post-operative period.

The advantages of the Thermarmour® blankets are that they are quick to apply to the patient and that numerous blankets only require a single heat source to "charge" with heat. However, their effectiveness without preheating still requires further exploration.

Future explorations should include the efficacy of Thermarmour® for the whole duration of the peri-operative period, different patient populations, its use in low income countries and those with limited access to reliable electricity sources and health economic evaluations ensuring the device is cost effective compared to other interventions.

Acknowledgements
The authors would like to thank all the nurses, anaesthetists and surgeons for their help and commitment in delivering this study.

The delivery of this research was supported by the Yorkshire and Humber Clinical Research Network.

Competing Interests
Funding to support the co-ordination of this study and the free provision of Thermarmour® blankets has been received by Interweave Textiles Ltd, manufacturers of Thermarmour. They had no input in the study design, conduct or publication.

The Spot On® monitors were provided free of charge from 3M however, the probes were purchased as per normal NHS routes.

NDS, CA, VA, LF, VM, ES – no competing interests declared.

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Figure 1. Thermarmour® blanket.

Figure 2. CONSORT diagram of patient recruitment.

Figure 3. Figure 3 Mean Temperature (°C) differences at 40 and 60 minutes. Values are means with error bars for two-sided 95% Confidence Intervals. The non-inferiority margin is represented by a solid line set at 0.3°C.

Thermarmour image

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Figure 2

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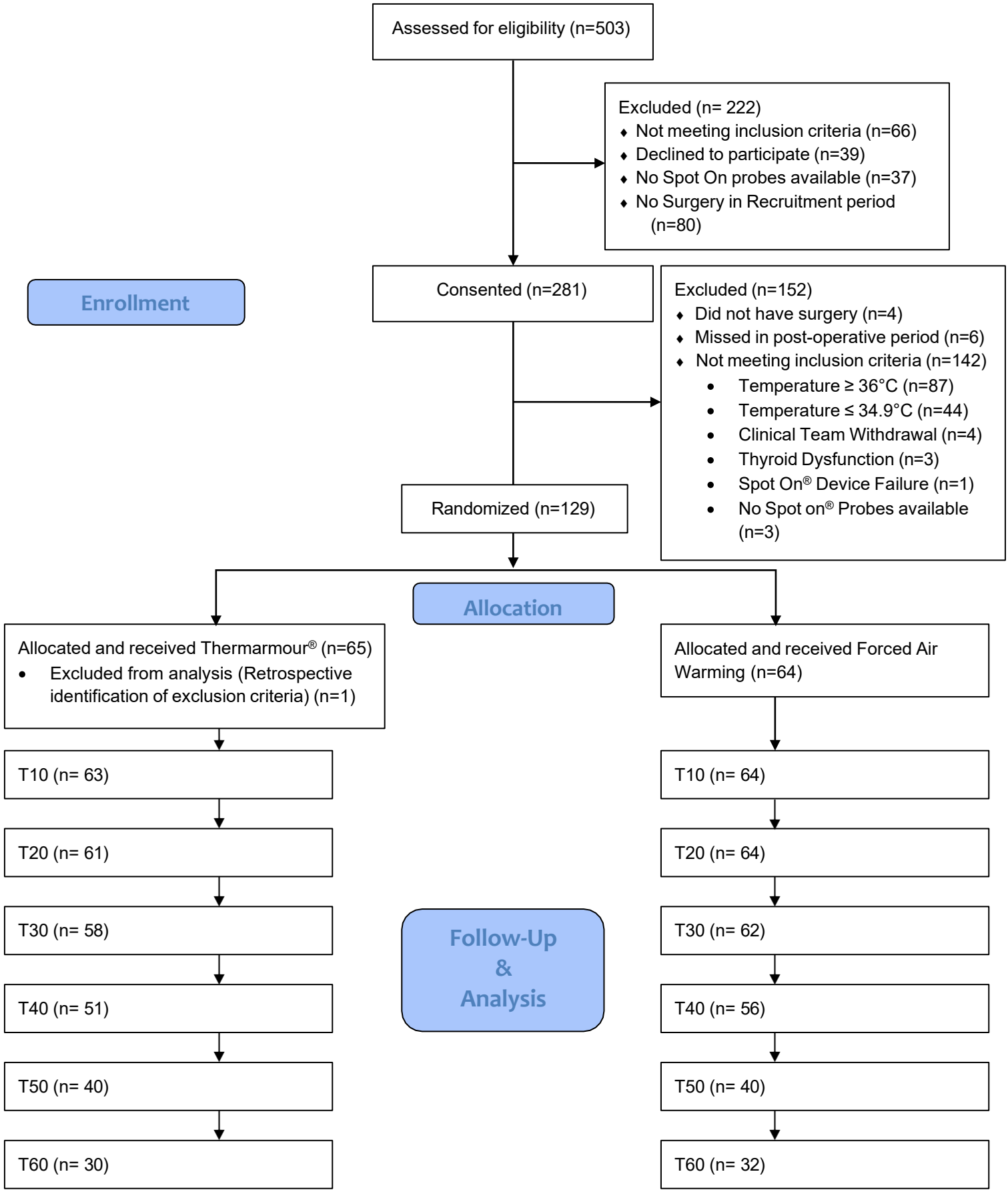

Figure 3

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