ARIA Trial

A randomised controlled trial to assess the clinical-, technical- and cost-effectiveness of a cloud-based, ARtificially Intelligent image fusion system in comparison to standard treatment to guide endovascular Aortic aneurysm repair

Statistical Analysis Plan
Version 1.0 (finalised 30/06/2022)
Using protocol version 1.1

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Health Economics Analysis Plan (HEAP) is detailed in a separate document.

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A) QUANTITATIVE ANALYSIS PLAN

1 Description of the trial

The key objective of the ARIA study is to evaluate the clinical, technical and cost-effectiveness of a novel type of CE-marked medical device (Cydar EV) to plan and guide endovascular aortic aneurysm repair. Cydar EV, which is comprised of real-time cloud computing, artificial intelligence (AI) and computer vision, will be evaluated against the standard of care for.

The study aims to enrol 340 participants in a phase 3, multicentre, open-label, two-group, randomised controlled surgical trial.

1.1 Principal research objectives to be addressed

Hypothesis: For patients with Abdominal, or Thoraco-abdominal, Aortic Aneurysm, use of Cydar EV for planing and surgical guidance during endovascular aortic aneurysm repair results in shorter procedure time and compared with the standard procedure.

Aim: To determine the safety and efficacy of Cydar EV in endovascular aortic aneurysm repair.

1.1.1 Primary objectives

To estimate:

- If there is a statistically significant difference between the treatment groups in terms of the procedure time of endovascular aortic aneurysm repair.

1.1.2 Secondary objectives

To estimate:

1. **Procedural efficiency**, as assessed by:
    - Anaesthetic duration
    - X-ray dose per procedure
    - Contrast dose per procedure
    - Consumable use per procedure
2. **Technical effectiveness**, as assessed by:
    - Proximal and distal seal zone at least 10mm and no evidence of endoleak
3. **Patient outcomes**, as assessed by:
    - Length of HDU admission
    - Length of ITU admission
    - Post-operative total length of hospital stay

- 30-day mortality
- Re-intervention – primary hospital visit / further admission (HRG/procedure code)
- Adverse events (category, LoS, HDU, ITU, general ward)
- Quality of life

4. **Cost effectiveness**, as assessed by:
    - Total resource use and costs
    - Quality-Adjusted Life Years (QALYs)
    - Incremental cost per QALY

1.2 Trial design and flowchart

Multi-centre, open label, two-armed, parallel groups randomised controlled surgical trial that assigns patients with a clinical diagnosis of abdominal aortic aneurysm and/or thoraco-abdominal aneurysm suitable and fit for endovascular treatment, to either repair using standard treatment or treatment using Cydar-EV.

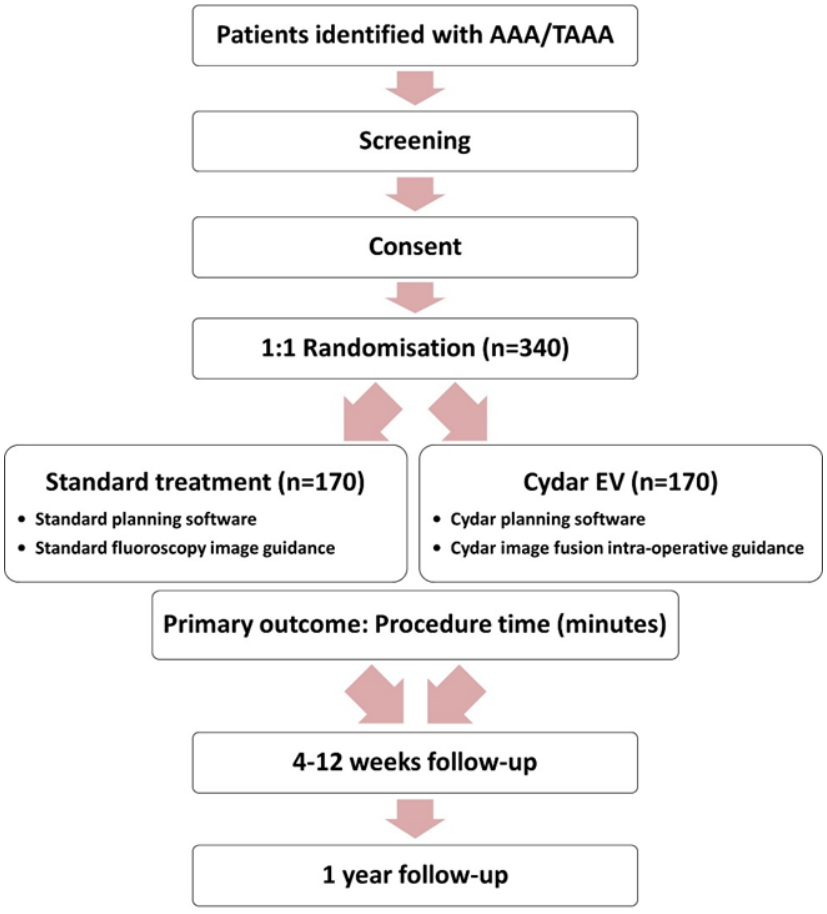

Figure 1: Trial design flow diagram

1.3 Method of allocation into groups

Once baseline assessments are complete, participants will be randomized in a 1:1 ratio using the method of minimisation. Randomisation is at the patient level and is performed using a web-based bespoke randomisation system set up by the King's Clinical Trials Unit (KCTU) at King's College London. Randomisation is minimised by the following factors:

- Surgeon
- Procedure urgency: emergency or elective
- Procedure type: simple (repair of infra-renal aneurysm +/- internal iliac embolisation) or complex (all other types of AAA and TAAA repair, to include branched and fenestrated devices)

The procedure is as follows: On receipt of the baseline questionnaire, the Trial Co-ordinator electronically submits details of each participant to the CTU. This includes: participant ID number, site, initials and date of birth. The system immediately notifies the relevant study nurse and records the randomisation outcome. The Trial Co-ordinator does not receive the randomisation outcome.

1.4 Study duration and frequency of follow up

Participants will be enrolled for a total period of 52 weeks (from baseline treatment to last visit). During that time, participants will be evaluated pre-discharge then invited for two followed up visits at week 4-12 and week 52.

1.5 Visit window

Participants will be seen in routine NHS follow up clinics. If visits have not been scheduled by the end of the week 4-12 and week 52 visit windows, the study site staff will contact the participants by telephone to collect the EQ-5D (telephone version) and attempts will continue to schedule a follow up visit. Data will be collected and entered, even if follow up clinic assessments are outside the optimal visit windows.

1.6 Data collection

The trial will randomize 340 patients with AAA and/or TAAA. After giving fully informed written consent, patients will be screened for participation in the study. Patients should fulfil the following criteria to be eligible for enrolment:

1.6.1 Eligibility screening

Inclusion criteria

1. Clinical diagnosis of AAA or TAAA suitable for endovascular treatment, as determined by CT imaging and a local treating team multidisciplinary review.
2. Patient is confirmed fit for endovascular repair as determined by the operating team
3. CT imaging must be in accordance with 'Cydar EV: Instructions for Use' i.e. scans should have the same slice thickness and intervals as the original scan acquisition, must not have any missing slices or discontinuities, must include

the pelvis and whole vertebrae including the spinous processes and must not use gantry tilt (this will be done post-consent)

4. Written informed consent (patients lacking capacity or unable to speak English will not be enrolled)
5. Age 18 years and above at the time of consent

Exclusion criteria

1. Patients unable to provide written informed consent

1.6.2 Efficacy Measures

The following outcomes will be reported.

Primary Measures

- Procedure duration (in minutes), as the time between insertion of the first wire (after percutaneous access achieved, if applicable) at the beginning of the endovascular procedure to the last frame of the completion angiogram.

Secondary Measures

1. **Procedural efficiency:**
   a) Anaesthetic duration – the time between the beginning of induction and the end of emergence. This will be documented at the time of the procedure by the local research team in minutes.
   b) X-ray dose per procedure –fluoroscopy time (FT) (seconds), dose area product (DAP) ($Gy.cm^2$) and cumulative air kerma (CAK) (mGy) should be recorded and documented at the time of the procedure by the local research team. The imaging system used should also be recorded.
   c) Contrast dose per procedure – the volume (ml) and concentration (mgI/ml) of the iodinated contrast material used should be recorded by the local research team at the time of the procedure in minutes.
   d) Consumable use in the operating theatre for endovascular aortic aneurysm repair – name of device, unit and quantity used, blood products used; details to be completed by nurse in the operating theatre or research nurse at the time of the procedure using a Source Data Worksheet.
2. **Technical success**:
   e) Proximal and distal seal zone at least 10mm and no evidence of endoleak. This will be documented by the imaging CoreLab team on review of the CT images acquired post-operatively and at 4-12 weeks and at 52 weeks.
3. **Patient outcomes**:
   f) Length of ITU/HDU admission – date and time from admission to date and time of discharge from ITU/HDU; documented by the local research team during the time of admission; ITU and HDU admissions should be documented separately
   g) Postoperative length of hospital stay – date of procedure to date of discharge from hospital (nights); documented by the local research team during the time of admission.

h) 30-day mortality – death of the participant within 30 days of the primary procedure; documented by the local research team; to include date of death (dd/mm/yy) and cause.
i) Re-intervention – any procedure open surgical or endovascular undertaken within one year of the primary endovascular aortic aneurysm repair procedure (binary outcome). The type, timing and number of procedures should also be recorded by the local research team.
j) Adverse events – hospitalisation for any reason within one year of the primary endovascular aortic aneurysm repair; the type of event should be documented and classified as one of the following: musculoskeletal, urological, neurological, ophthalmological, cardiovascular, gastro-intestinal, hepato-pancreato-biliary, dermatological or other by the local research team, with information captured to understand if linked to re-intervention (section 'i' above). For each hospitalisation the following should also be captured:
    i. Day case, Elective, Non-elective
    ii. Length of hospital stay - date of admission to date of discharge (nights)
    iii. Length of ITU/HDU admission (if applicable) - date and time from admission to date and time of discharge from ITU/HDU; ITU and HDU admissions should be documented separately
k) Quality of life – differences in quality of life between intervention and the comparator group, and changes in quality of life post-surgery will be measured using data from the patient-completed EQ5D-3L instrument.[1] EQ-5D-3L is a validated measure of health-related quality of life, consisting of a five-dimension health status classification system and a separate visual analogue scale. EQ-5D-3L data will be obtained through face-to-face or telephone interview with the participant at baseline, pre-discharge, 4-12 weeks and at 12-months follow up. Patients will complete the questionnaires with the support of the local research team

1.6.3 Safety Outcome Measures

Safety will be evaluated by assessing adverse events (AEs), serious adverse events (SAEs), and important medical events (IMEs). The percentage of participants with observed AEs will be reported within each group with 95 % confidence intervals. The trial will specifically report the incidence of reintervention (open surgical or endovascular), endoleak, rupture of AAA/TAAA, limb thrombosis, migration, access vessel complication, myocardial infarction, stroke, renal injury, and amputation.

1.7 Sample size estimation (including clinical significance)

We were not aware of any known minimum clinically important difference (MCID) and part of the aim of the study is to better characterise the clinical benefit to patients. The study is instead powered on the basis of a minimum economically meaningful difference. Previous work at Duke[2] reported data on the primary outcome, procedure time, and found a mean difference of 22.5 minutes (17%) for patients with an abdominal aortic aneurysm treated with Cydar-EV 109.6 (34.2) and standard 2D fluoroscopy imaging 132.1 (69.2) minutes. This is a meaningful difference in the NHS context as this time reduction per case would allow four rather than three EVAR procedures to be performed per day, which is a productivity increase of 33% at the same capacity. The SD for procedure time increases with the mean and so we have assumed a t-test for ratio of means 1.2 (fold change), assuming a lognormal distribution for the calculations. Therefore, a sample size of 153 patients per arm with a 1:1 allocation ratio (2 x 153 = 306) would give us 90% power at the 2-sided 5% significance level to detect this difference (PASS 15 Power Analysis and Sample Size

Software (2017)). Since our primary outcome measure requires the procedure to be completed, we need to inflate the sample size for possible: i. loss post randomisation, pre-procedure (est 7.5%); and ii. on-table death and cross-overs (where surgeons may use the intervention in a control arm patient (see section 4.5) and additional assistance is required to complete the operation) (est 2.5%). These inflate the sample size to 170 per arm. The final randomisation target is therefore 2 x 170 = 340. The Duke data also showed using Cydar-EV in TAAA showed larger reductions in operating time than for AAA. We have powered on the more conservative difference since the relative proportions of AAA/TAAA patients anticipated in our proposed trial is unknown.

1.8 Brief description of proposed analyses

Analyses will be carried out by the trial statistician. In the first instance, the primary analysis will be per-protocol (PP) based on the received intervention rather than the allocated group. The primary analysis will be conducted after completion of first follow-up (at 4-12 weeks) which will include procedure time as well as the secondary outcome data available at this time. We will conduct further analyses of secondary outcomes at the completion of 52 weeks follow-up for all the patients.

2 Data analysis plan – Data description

2.1 Recruitment and representativeness of recruited patients

Recruitment, randomisation, and follow-up for ARIA will be summarised by arm in a CONSORT flow-diagram.[3] This will include the main reasons for there being missing data (withdrawal, lost to follow up) by stages of the trial, and will also include the numbers for whom this occurs per arm. Also included will be the number randomised, the number received the treatment, who comprise the PP population, and the numbers followed-up to be in the analyses of secondary outcomes and safety evaluation.

2.2 Baseline comparability of randomised groups

Baseline characteristics of each group will be summarised as mean and standard deviation for continuous variables with median and interquartile range for highly skewed data, and count and percentage for categorical variables. No significance testing on baseline variables will be performed.

The baseline characteristics will include patient demographics, randomisation (minimisation) stratifiers, medical history, intraoperative processes, and other baseline clinical measures. This will allow an assessment of whether there is clinically important imbalance in any variables.

2.3 Loss to follow-up on outcome data

The number of patients with missing primary outcome (procedure time) is expected to be few but will be noted. The baseline characteristics of those with unrecorded primary outcome will be compared statistically to those with complete data using appropriate univariate statistical tests. The proportions of participants with any missing data will be summarised by variable in each arm and at each time point. The reasons for withdrawal from the trial will be summarised in the CONSORT flow diagram.

Our study size and power calculations allow for a 10% loss at the primary endpoint. To address any missingness that occurs, we will conduct a sensitivity analysis of the primary outcome that adjusts for any factors shown to be different between those present and those with full primary outcome data.

2.4 Adverse event reporting

Adverse events (AE), serious adverse events (SAE), and important medical events (IME) will be summarised as counts and percentages with 95% confidence intervals by trial arm. In addition, event type, intensity, and relatedness to the study intervention will be summarised.

2.5 Descriptive statistics for outcome measures

Efficacy measures (listed under section 1.6.2) will be summarized as mean and standard deviation for continuous outcomes, with median and interquartile range where there is extreme skewness, and count and percentage for categorical outcomes.

3 Data analysis plan – Inferential analysis

3.1 Main analysis of treatment differences

3.1.1 Analysis of primary outcomes

The principal analyses of primary outcome will be per-protocol (PP). All randomized patients in these analyses will be classified according to their received intervention after randomization. The difference between treatment groups in terms of procedure duration (as measured between insertion of the first wire after percutaneous access achieved, if applicable, at the beginning of the endovascular procedure to the last frame of the completion angiogram) will be tested. It is expected to observe a skewed distribution in the primary outcome and therefore, if necessary and possible, the data will be normalised using an appropriate transformation. The data will then be analysed using linear regression techniques with stratification (minimisation) factors included as covariates. If a suitable transformation cannot be found the data will be analysed using quantile regression to allow us to include the addition of the stratification factors as covariates. Group difference estimates and associated confidence intervals will be reported at a two-sided 0.05 significance level.

3.1.2 Analysis of secondary outcomes

A similar analysis will be undertaken for the secondary outcomes including quality of life scores. Binary outcomes will be compared between arms using logistic regression adjusting for stratification factors.

Outcomes will be reported as adjusted differences in means (or median) or odds ratios for continuous and binary data, respectively. All tests will be two sided and will be assessed at the 5 % significance level. Safety outcomes will be reported as patient proportions and rates within and between arms with 95 % confidence intervals using exact methods where appropriate.

3.1.3 Additional analyses

- Image analysis – analysis of technical outcome

CT image data acquired pre-operatively and at the two post-operative intervals will be uploaded to the system for analysis. All image data will be reviewed independently by two experienced clinicians blinded to the image guidance method used during endovascular aortic repair. Anatomical measurements will be performed with central luminal line reconstructions using dedicated software. Measurements will include: aneurysm size, aortic neck (diameter, length,α and β angulation), iliac diameter and stenosis, distance from the lowermost renal artery to the beginning of the covered part of the endograft; the length of the proximal sealing zone, length of the distal sealing zone and detection of endoleak. Technical success will be defined as proximal and distal seal zone at least 10mm with no evidence of endoleak.[4]

- System efficiency

A key link between the primary outcome measure (procedure time) and the cost-effectiveness of the intervention is measured in terms of improvements in the planning and utilisation of operating theatre resources. The average procedure time in England for a standard EVAR procedure is 110 minutes. Assuming operating theatre capacity of 420 minutes (7 hours) daily, it would currently be possible to complete three EVAR procedures daily with an allowance for turn-around time. Assuming a similar reduction in procedure time as was observed in the Duke University study (18%), with Cydar-EV it would be possible to complete four procedures daily with the same capacity, an increase of 33%. The HRG EVAR tariff can be used as a proxy for the value to the NHS of the additional procedure. Because Cydar-EV is also expected to reduce variability in procedure times there should also be a reduction in the number of cancelled operations because of over-runs, and more predictability in waiting list planning and bed occupancy.

We will explore the implications of improvements in system efficiency by comparing the distributions of procedure times for Cydar-EV and standard fluoroscopy and assessing these against current capacity constraints (e.g. operating theatre capacity, turn-around times etc). We will also assess the potential implications of any 'learning curve' effects in the procedure times for Cydar-EV. We will use these analyses to develop a series of scenarios which capture the potential impact on Cydar-EV on improving the planning and utilisation of operating resources in terms of costs and potential health consequences. The impact of these scenarios on the overall cost-effectiveness of Cydar-EV will be assessed using sensitivity analysis.

- Value of information

Decisions based on 12-month follow up (and the exploratory model based analysis) for Cydar-EV will be subject to uncertainty and there will always be a chance that the wrong decision could be made. If the wrong decision is made, there will be costs in terms of health benefit and resources forgone. The maximum amount the NHS should be willing to invest to further reduce remaining uncertainty in the decision can be informed by the expected value of perfect information (EVPI). EVPI evaluates the expected cost of current decision uncertainty, based on results from the ARIA trial, by accounting for both the probability that a decision based on existing evidence is wrong and for the magnitude of the consequences of making the wrong decision.

The EVPI estimates will be used to assess the potential value of further research and to inform future research priorities. EVPI also represents the maximum amount that a decision-maker should be willing to pay for additional evidence to inform this decision in the future. EVPI provides an upper bound on the value of additional research. This valuation provides an initial hurdle, acting as a necessary requirement for determining the potential efficiency of further primary research. Applying this decision rule, additional research should only be considered if the EVPI exceeds the expected cost of the research.

3.2 Statistical considerations

3.2.1 Missing outcome data

We will report missingness wherever present. Reasons for missingness may be important and these will be investigated using logistic regression of covariates on an indicator of missingness. In relation to the primary outcome variable, we will conduct an available case analysis then explore the sensitivity of results to missing data by conducting a worst-case best-case analysis. The sensitivity analysis will consider participants in the Cydar-EV group with missing outcomes having the shortest observed (from overall sample) operation time and participants in the control group with missing data having the longest, and then the opposite.

3.2.2 Method for handling non-compliance

Reasons for non-compliance will be noted and summarised. This may include device failure, surgeon error or failure to communicate correct randomisation allocation to the surgeon. The patient could only impact compliance if they express a wish to withdraw between randomisation and surgical procedure.

3.2.3 Method for handling non-conformity in randomisation

In the case that randomised treatment code is incorrectly applied by unforeseen reason, we will identify the patients potentially affected and establish which, if any, of those patients received the opposite treatment allocation to that randomised. Analyses will be per protocol, and baseline differences between treatment groups will be investigated, including randomisation (minimisation) stratifiers.

3.3 Exploratory analyses

Any examination of subgroups, not specifically identified in the protocol, will be considered exploratory in nature and will be clearly identified.

3.4 Interim analysis

The usual rationale for an interim analysis is to consider stopping the treatment (or the trial) however as this treatment is given at baseline, it is not possible to subsequently stop treatment for a given participant. There will be no planned formal interim analyses of the primary and secondary outcomes. The DMC will examine the recruitment rate, data completeness and monitor safety, and will recommend whether the study should continue, stop, be suspended, or be modified, based on their findings. If necessary for urgent safety reasons the Sponsor may stop or pause the trial immediately, without DMC review.

3.5 Software

Data management: An online data collection system for clinical trials (MACRO; InferMed Ltd) will be used. This is hosted on a dedicated server at King's College London and managed by King's CTU (KCTU). The KCTU Data Manager will extract data periodically as needed and provide these in comma separated (.csv) format.

Statistical analysis: Statistical software package R will be used for data description and the main inferential analysis.

B) SCHEDULE OF ASSESSMENTS AND MEASURES

Timepoint	Screening	Randomisation	Pre-surgery	Surgery	Pre-discharge	Week 4-12	Week 52	Ongoing
Registration Form & Consent	**X**							
Check Inclusion Criteria (if CT Image suitable for CYDAR)	**X**							
Full medical history and baseline demographics (smoking, ethnicity, routine bloods)	**X**							
EQ-5D-3L	**X**		**X***		**X**	**X**	**X**	
Intra-operative data				**X**				
ITU/HDU admission record					**X**			
Hospital admission record					**X**			
Post-operative CT aorta assessment						**X**	**X**	
30 day mortality				X	X	**X**		
Re-intervention record								**X**
Adverse event log								**X**
Status								**X**
Withdrawal								**X**
Concomitant treatment								**X**

**If more than 28 days since last EQ5D-3L.*

Amendments to version 1.0

Reference List

1. EuroQol Research Foundation. EQ-5D-3L User Guide, 2018. Available from: https://euroqol.org/publications/user-guides. .
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3. Moher D, Schulz KF, Altman DG, Group C. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomised trials. In: Elsevier; 2001.
4. Baderkhan H, Haller O, Wanhainen A, Bjorck M, Mani K. Follow-up after endovascular aortic aneurysm repair can be stratified based on first postoperative imaging. *British Journal of Surgery.* 2018;105(6):709-718.