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| Project Title | Comparison of demographics, clinical symptoms, and urodynamic findings between detrusor overactivity with detrusor underactivity patients under the age of 70 and those aged 70 or older | |
| Version Date | 09/11/2023 | |
| **This document is a protocol for a research project.** This study will be conducted in compliance with the NHMRC National Statement on ethical Conduct in Human Research (2007), the Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95) and any stipulations as outlined by the reviewing Human Research Ethics Committee. | | |
| Project Ethics Number  (Office Use Only) | | HREC/103156/Austin-2023 |

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1.1 – Project Classification

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| Please tick the correct classification for your project | Intention to publish in scientific journal and any samples taken are part of standard of care. This is classified as research, therefore requiring approval from Ethics Committee or their delegate. |
| No intention to publish, part of Organisation’s “Quality and Safety” continuous improvement processes and to be registered in the Projects and Improvements Database. This means you are exempt from Ethical Review but you cannot publish in a scientific forum. Register your QI project via Quality & Safety on the Projects and Improvements Database. |

1.2- Site Specific Investigators

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| Name | Site Department | Role e.g. Associate Investigator | Email |
| Jaraspong Vuthiwong | - Department of Urology, Austin Hospital, Heidelberg, Victoria, Australia  - Department of surgery, Faculty of medicine, Chiang Mai University, Chiang Mai, Thailand | Principal Investigator | jaraspong.vuthiwong@austin.org.au  jaraspong.vuthiwong@cmu.ac.th |
| Johan Gani | - Department of Urology, Austin Hospital, Heidelberg, Victoria, Australia | Associate Investigator | johan.gani@austin.org.au |
| Liang G Qu | - Department of Urology, Austin Hospital, Heidelberg, Victoria, Australia | Associate Investigator | liang.qu@austin.org.au |
| Stewart Whalen | - Department of Urology, Austin Hospital, Heidelberg, Victoria, Australia | Associate Investigator | stew.whalen@austin.org.au |

1.3 - Will you be working with anyone outside of the lead Site?

Please add any collaborators or stakeholders who are not based at and clearly state who will be the principal investigator at each additional site.

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| Name | Institution | Role e.g. Associate Investigator | Email |
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1.4 - Conflicts of Interest

Is there any affiliation or financial interest for any researcher in this project which might represent a perceived, potential or actual conflict of interest?

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| Yes  No | If yes, please explain. |

1.5 - Funding and Licence

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| Funding Source and Study Budget | No budget required as supported by site funds or in-kind support  Budget required, funded via external competitive grant (NHMRC, ARC, MRFF)  Budget required, funded by a commercial sponsor |
| Commercial in Confidence | Yes  No |

1.6 – **Site Specific Authorisation**

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| **Situation** | **Agreements Required** |
| Data to be shared outside of Austin Health | Yes, please contact the Office for Research to discuss whether an agreement is needed  No |
| PhD or Masters student using data towards their degree | Yes, please contact the Office for Research to discuss whether an agreement is needed  No |
| Access to biobank/ research database outside of Austin Health | Yes, I have a letter of support from the biobank/research database to use their data  No, I am in the process of obtaining a letter of support to use their data  No, I am not accessing a biobank/research database outside of Austin Health |
| Investigator competency check | **Only provide the following if you are recruiting patients and/or staff:**  CVs attached or submitted in the last 2 years  [Good Clinical Practice (GCP)](https://genesisresearchservices.com/education/gcp-ich-course/) certificates attached or submitted in the last 2 years  Working with Children’s Check attached for projects working with people under 18 years of age |

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2.1- Aims and Background

Use referenced literature to describe the gap in knowledge that your project will address.

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| Within our project we plan aim to retrospectively compare demographic characteristics, clinical presentations, and urodynamic findings between two age groups of DO-DU patients: those younger than 70 years and those aged 70 years or older.The current literature demonstrates that detrusor overactivity with detrusor underactivity (DO-DU), originally characterized in 1987 as a leading cause of urinary incontinence in frail patients1, continues to pose challenges in terms of understanding its demographics, clinical characteristics, and urodynamic findings. The pathophysiology and etiology have not been well defined due to insufficient research. A comprehensive profile of DO-DU also remains elusive. DO-DU represents a complex form of voiding dysfunction. It can lead to severe lower urinary tract symptoms; nevertheless, there is little published research describing the clinical course of DO-DU. DO-DU diagnoses have predominantly occurred in individuals in their late 70s, with up to 35% of women aged 80 years or older exhibiting DO-DU in urodynamic assessments2. Griffith et al3. reported on 73 elderly incontinent DO-DU patients, with a mean age of 79 years (ranging from 60 to 98 years). Similarly, Stav et al.4 documented 151 women with DO-DU, demonstrating a mean age of 73.2 (+/-17.3) years. Furthermore, Gammie et al.5examined 123 men and 136 women with DO-DU, revealing median ages of 70 (62-76) years and 64 (53.4-74.5) years, respectively. Despite initially described in frail institutionalized elderly, we have observed a rising incidence of DO-DU diagnoses in younger populations, a phenomenon that merits further investigation. Therefore, the objective of this study was to conduct a comparative analysis of the demographics, clinical manifestations, and urodynamic observations among patients diagnosed with DO-DU, dividing them into two age groups: individuals aged younger than 70 years and those 70 years or older. Our hypothesis predicts that the younger group would exhibit a higher prevalence of risk factors in their demographic data, while the elderly group will demonstrate a greater incidence of urgency and urge incontinence, likely attributed to limited mobility. Additionally, the urodynamic findings are expected to reveal less bladder contraction in the elderly group, which can be attributed to the effects of advanced age.  Reference   1. Resnick NM, Yalla SV. Detrusor hyperactivity with impaired contractile function. An unrecognized but common cause of incontinence in elderly patients. JAMA 1987;257:3076-81. 2. Valentini FA, Robain G, Marti BG. Urodynamics in women from menopause to oldest age: what motive? What diagnosis? Int Braz J Urol [Internet]. 2011;37(1):100–7. Available from: <http://dx.doi.org/10.1590/s1677-55382011000100013> 3. Griffiths DJ, McCracken PN, Harrison GM, Gormley EA, Moore KN. Urge incontinence and impaired detrusor contractility in the elderly. Neurourol Urodyn 2002;21(2):126-31. 4. Stav K, Shilo Y, Zisman A, Lindner A, Leibovici D. Comparison of lower urinary tract symptoms between women with detrusor overactivity and impaired contractility, and detrusor overactivity and preserved contractility. J Urol 2013;189(6):2175-8. 5. Gammie A, Kaper M, Steup A, Yoshida S, Dorrepaal C, Kos T, et al. What are the additional signs and symptoms in patients with detrusor underactivity and coexisting detrusor overactivity? Neurourol Urodyn [Internet]. 2018;37(7):2220–5. Available from: <http://dx.doi.org/10.1002/nau.23565> |

2.2 – Project Description

This section is in line with [National Statement 1.1 (b), (d), (e) and (f)](about:blank#toc__95) to demonstrate that the research has merit.

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| This project uses a quantitative research methodology that will include the following data collection method/s:  Retrospective audit of medical records  This methodology is appropriate to answer the research questions/meet the research aims because it can compare demographic characteristics, clinical presentations, and urodynamic findings between two age groups of DO-DU patients: those younger than 70 years and those aged 70 years or older.  **Retrospective audit of medical records**  Data will be collected using review of electronic and paper medical records. Medical Records and/or medical databases will be accessed by Jaraspong Vuthiwong using electronic and paper medical records from urodynamic room, Department of Urology, Austin Hospital, Heidelberg, Victoria and will be stored in password protected Excel spreadsheet. The following data points will be obtained:   * Age * Gender * Past medical history components such as * diabetes mellitus * stroke * multiple sclerosis * spinal disease * Parkinson's disease * neurogenic disorders * prior pelvic surgeries * prior incontinence surgery * a history of pelvic radiation. * The presence of lower urinary tract symptoms, including both storage and voiding symptoms * Self-reported instances of abdominal straining * Recurrent UTIs * Urodynamic parameters, including first sensation of bladder filling, volume of normal desire to void, volume of strong desire to void, maximum cystometric capacity, compliance of the bladder, maximum flow rate during voiding (Qmax), detrusor pressure at the point of maximum flow (PdetQmax), voiding volume (VV), postvoid residual urine (PVR), voiding efficiency (VE), bladder contractility index (BCI) presence of urodynamic abdominal straining.   **Data & Statistical Analysis Plan**  By reviewing 2500 medical records, the total sample size for the project is approximately 200 cases.  Specifically, this sample size is comprised of the following samples from each of the participant groups:   1. Participant Group 1 DO-DU patients under the age of 70: approximately 100 cases 2. Participant Group 2 DO-DU patients under the aged 70 or older: approximately 100 cases   This sample size is sufficient to meet the research aims and answer the research questions because this study does not intend to generalise to broader populations, but to gain an in-depth understanding of the topic and this sample size will allow for broad representation of perspectives on the topic.  The distribution of baseline characteristics, clinical symptoms, and urodynamic parameters were compared between patients <70 years and ≥70 years. Chi-square statistics were calculated for comparing proportions, and Wilcoxon rank sums were calculated for continuous and ordinal data. The calculations were conducted using STATA version 15.1, developed by StataCorp in College Station, TX, USA. In this study, a significance level of 0.05 was used to determine statistical significance. |

**2.3 Sustainability and Scalability Plan**

Please state how, if successful, the project can be embedded into business as usual and/or how it would benefit other clinical groups.

This project will be able to inform the demographic characteristics, clinical presentations, and urodynamic findings for DO-DU patients. These findings are essential for providing effective care, improving patient outcomes, and advancing research and treatment options in the field of urology.

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3.1 – **Inclusion and Exclusion Criteria**

Please outline the criteria that will be used to select potential participants. In line with the National Statement, items [1.4 (a)](about:blank#toc__95) [3.1.12](about:blank#toc__438) and [3.1.14](about:blank#toc__438).

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| **Selection/Inclusion criteria for this study include**:   1. Over the age of 18 years underwent urodynamic study at Austin Health between 2012 and 2022. 2. Patient diagnosed with DO-DU from urodynamic study.   **Exclusion criteria include:**   1. A lack data for analysis. 2. Patients who have undergone intravesical botulinum toxin injections within the preceding 6 months. |

3.2- Recruitment

Please outline the methods used to recruit participants to the study. The information must outline the following to address National Statement items [3.1.12-3.1.22](about:blank#toc__417).

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| **Medical Records**  The research team will access patient records and urodynamic report at Austin health from 2012-2022. |

3.3- Consent

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| **Medical Records**  As part of recruitment, we will view patient medical records to determine suitable participants for this study. This data was collected as part of routine standard of care. We will access the information from the participants medical record as per section 2.2.  **Waiver of Consent for Medical Records and/or Biospecimens**  We are requesting to access retrospective records/samples from the electronic medical records. We plan to access records/samples that were taken from the participant between 01/2012 to 12/2022.  Therefore, as per section 2.3.10 of the National Statement we are requesting a waiver of consent due to the following reasons:   * it is impracticable to obtain consent due to the quantity and accessibility of records. * the benefits from the research justify any risks of harm associated with not seeking consent because these findings are essential for providing effective care, improving patient outcomes, and advancing research and treatment options in the field of urology. * there is sufficient protection of their privacy. All data will be stored, as per Section 3.4 and 3.5 of this document. When the data is the shared via publication or presentation it will be deidentified and aggregated to ensure that no singular individual can be identified. * there is an adequate plan to protect the confidentiality of data, as per Section 3.4 and 3.5 of this document.   Additionally, the project also meets the following voluntary requirements:  involvement in the research carries no more than low risk to participants.  there is no known or likely reason for thinking that participants would not have consented if they had been asked  in case the results have significance for the participants’ welfare there is, where practicable, a plan for making information arising from the research available to them (for example, via a disease-specific website or regional news media). As there is no patient contact as part of this project, patients will not be individually informed of the outcome of this project. However, we do intend to publish the results to the public.  there is no possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants of any financial benefits to which they would be entitled.  the waiver is not prohibited by State, federal, or international law. |

* 1. – Risks

This is to address [National Statement 2.2.1 – 2.1.8](about:blank#toc__155). Examples of discomforts include: minor side-effects of participating in the research in general (e.g., headaches), discomforts related to being asked about particular aspects of one’s personal or social lives, and/or anxiety induced by providing answers during an interview or in answering a survey.

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| **Risk Management to access Medical Records/Databases**  The medical record review will not pose any risk because medical records will be accessed by a named investigator on this project, who has rightful access to the medical records. Identifying information such as hospital number and date of birth will not be collected. This means the data will be collected in a de-identified format. |

* 1. – Data & Confidentiality Management

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| Data will be stored at: Urodynamic room, Department of Urology, Austin Hospital, Heidelberg, Victoria  Please select one of the following:  De-identified data will be stored for this project. Individual identifiers will be removed from the data upon collection to ensure that all data stored for this project is de-identified. Data will be kept secure at all times by being either password protected or securely locked away at the institution as stated above. All data, both electronic and paper, will be kept for a maximum of 7 years from the time of collection. After 7 years, all data will be destroyed through deletion of electronic files or through shredding or placing files into confidential waste bins for paper data.  Re-identifiable data will be stored for this project. Upon collection, participant data will be allocated a unique identifier which will allow for re-identification if needed. The data coding document containing the key for re-identification will be kept secure at all times with only named investigators having access. The participant will only be identified by investigators if deemed crucial to the study’s function. Data will be kept secure at all times by being either password protected or securely locked away at the institution as stated above. All data analysed and published from this project will not allow for patient identification. Participant information will be stored for a maximum of 7 years from the time of collection. All data will be destroyed after 7 years through deletion of electronic files or through shredding or placing files into confidential waste bins for paper data.  Neither of the above. Please clarify below how data will be collected and stored securely. |

* 1. Publications & Dissemination of Results

This section will answer the sections addressed in the [National Statement item, 1.1 (d)](about:blank#toc__111).

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| **Publication & Dissemination of Results for Medical Record Review and/or Secondary Analysis of Biospecimens**  The person whose data and/or biospecimens are used will not be provided with a summary of findings. This is because there is no patient contact as part of this study. |

* 1. – Declaration

By submitting this application **all** investigators declare that they have:

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| (Please tick this box to confirm your declaration) | By submitting this application, we, the Principal Investigator, Co-Investigators and Student Investigators, declare the following:   * All information in this application and supporting documentation is correct and as complete as possible; * I have read and addressed in this application the requirements of the National Statement and any other relevant guidelines; * I have familiarised myself with, considered and addressed in this application any relevant legislation, regulations, research guidelines and organisational policies; * All relevant financial and non-financial interests of the project team have been disclosed; and   understand that we cannot commence data collection until we receive a formal approval letter from Austin Health Human Research Ethics Committee or one of its Low-Risk Committee;   * I will abide by the terms and conditions set by the Austin Health Human Research Ethics Committee or on of its Low-Risk Committee; * I will ensure that the qualifications and/or experience of all Austin Health personnel involved in the project are appropriate to their role and/or to the procedures performed; * I will ensure that appropriate approvals and/or approvals from external organisations or agencies will be obtained and that any imposed conditions will be observed; * In the capacity of principal investigator, I have reviewed this application and I will provide appropriate supervision to the student(s) in accordance with the arrangements specified in this application and those associated with the student’s educational program. |