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| A.STUDY NO | |
| B.STUDY INFORMATION | |
| **Study Title English & Arabic):** | Various clinical presentations of Congenital hypothyroidism and consequences among children visited King Abdul-Aziz University Hospital (KAUH) in western region, Saudi Arabia |
| **Principal Investigator** | Prof. abdulmoein Agah |
| **Title /Positions** | Professor and Consultant , pediatric endocrinology |
| **Principal Investigator’s experience conducting research at study site(s) in relation to the proposed study:** | |
| **Department:** |  |
| **Mailing Address:** |  |
| **Email:** | [aagha@kau.edu.sa](mailto:aagha@kau.edu.sa) |
| **Phone:** | 0505590459 |
| **Additional Contact Person:** | Rogaya Alshugair |
| **Mailing Address:** |  |
| **Email:** | [rogaya1992@gmail.com](mailto:rogaya1992@gmail.com) |

**C.** STUDY Type. Check all that apply

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| **Non Intervention**  **Case Report**  **Case series**  **Cross sectional**  **Case Control**  **Cohort**  **Qualitative Research**  **Retrospective Record Review**  **Other, explain** | | **Intervention**  **Cross sectional**  **Case Control**  **Cohort**  **Clinical Trial**  **Animal Study**  **Other, explain:** |
| **D.** STUDY Area. Check all that apply  Behavioral/Psychosocial Intervention  Tissue/Data Repository(( DNA/ Genetic Analyses))  Investigational Drug or Biologic (Complete Appendix A)  Investigational Device (Complete Appendix A)  Secondary Data/Specimen Analysis  Other, explain: | | |
| E. PROCEDURES/STUDY POPULATIONS REQUIRING ADDITIONAL REVIEW. Check all that apply. | | |
|  | Waiver of the consent process | |
|  | Research including vulnerable populations, e.g., children | |
|  | Genetic Analyses | |
|  | The use of any biohazards | |
|  | Drugs/Biologics (Use of drugs/biologics other than the use of approved drugs/biologics in the course of medical practice)  *If so, complete and submit Appendix A: Drugs, Biologics and Devices* | |
|  | Devices (Evaluation of the safety or effectiveness of a device or used as a comparator)  *If so, complete and submit Appendix A: Drugs, Biologics and Devices* | |
| F. FUNDING SOURCE(S). List all funding sources here. If none, check here and skip to section F | | |
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| G. Names of all research personnel involved in the design, conduct, or reporting of the research | | | | |
| Name | Contact Information Email/Telephone | Role in the research | Contact with participants? | Involved in the consent process? |
| Dr.Dareen Saleh Alghalbi | [Dr.dareen@hotmail.com](mailto:Dr.dareen@hotmail.com)  0567665330 | Co. investigator/ data collector |  |  |
| Dr.Shahad Jamil Ashgar | [she200913@hotmail.com](mailto:she200913@hotmail.com) | Co. investigator/ data collector |  |  |
| Dr.Arwa Ali Badakhan | [arwa.badukhon@gmail.com](mailto:arwa.badukhon@gmail.com) | Co. investigator/ data collector |  |  |
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| |  | | --- | | 1. Background | | One of the most common causes of non endemic goiter and acquired hypothyroidism in children and adolescents is autoimmune thyroiditis (AT) [1]. Autoimmune thyroiditis mostly occurs in 2% of the female population especially in early to mid-puberty, while, 0.2% of the male population are affected.[2]. A combination of genetic susceptibility and environmental encounters leads to breakdown of tolerance but the exact etiology is still unknown [2,3] . Treatment should be started as soon as possible to prevent neurological and growth complication and development of thyroid disease where is chronic autoimmune thyroiditis (AT) is the most common cause of thyroid disease in children [2] | | * 1. **((Rationale ))Why this research is important and how it will add to existing knowledge:**   The research is important because it aims to investigate the clinical manifestations of autoimmune thyroiditis and associations with other autoimmune diseases | | 1. Study Location | |  | | 1. Study Objectives | | * 1. **Objectives/Aims:**   investigate the clinical manifestations of autoimmune thyroiditis (AlT) , associations with other autoimmune diseases, and long term follow up over 12 years at KAUH. | | 1. Study Design | | * 1. **Study design (e.g., double-blind:**   Retrospective study. | | * 1. **Primary study endpoint(s):**   investigate the clinical manifestations of autoimmune thyroiditis (AlT) , associations with other autoimmune diseases, and long term follow up over 12 years at KAUH. | | * 1. **Secondary study endpoint(s), if any:** | | * 1. **Primary safety endpoint (study stopping rules):** | | * 1. **Study duration:** | | 1. Participant Selection and Withdrawal | | * 1. **Source of Participants:**   KAUH follow up children at endocrinology clinic | | * 1. **Inclusion criteria:** | | * 1. **Exclusion criteria:** | | * 1. **Participant recruitment (describe recruitment method):** | | * 1. **Procedures for obtaining informed consent:** | | * 1. **Early withdrawal of participants (when and how to withdraw participants, data collection and follow-up for withdrawn participants):** | | 1. Study Procedures | | * 1. **Study visits including procedure/tests involved at each visit (e.g., blood test, x-rays, questionnaires):** | | * 1. **Follow-up evaluation:** | | 1. Statistical Plan | | * 1. **Statistical methods:** | | * 1. **Sample size determination (Include power calculations or provide justification for their absence, e.g., pilot/feasibility study):** | | * 1. **Participant population for analysis:** | | * 1. **Data management (data collection and data entry):** | | 1. Data Handling and Record Keeping | | * 1. **Confidentiality (how and where is data stored, and who will have access):** | | * 1. **List source documentation that is used to capture data (e.g., hospital records, clinical and office charts, laboratory notes, memos, subjects’ diaries or evaluation checklists, pharmacy dispensing records, etc)**   Hospital records | | * 1. **Record retention (where and for how long):** | | 1. Study Finance and Insurance | | * 1. **Funding source:** | | * 1. **Investigator financial conflicts of interest, if any:** | | * 1. **Payments to participants:** | | 1. Dissemination of Results | | * 1. **Publication Plan (if not addressed in a separate agreement):** | | * 1. **Plan to share individual and/or aggregate results with participants, e.g., results letter:** | | **11** References | |  | | **12** Attachments | |  | | **13** SENDING/RECEIVING SPECIMENS/DATA TO/FROM RESEARCH COLLABORATORS OUUTSIEDE KAU: | | **13.1 Specimens/data to be sent and/or received:** | | **13.2 Variables included with specimens/data:** | | **13.3 Who will send and/or receive data:** | | **13.4 How will specimens/data be transported:** | | To Be filled in Clinical Trial | | **14** INVESTIGATIONAL PRODUCT (E.G.,DRUG,DEVICE): | | **Description:** | | * 1. **Treatment regimen:** | | * 1. **Compare Treatment to Local standard of care:** | | * 1. **Participant compliance monitoring:** | | * 1. **Prior and concomitant medication/treatment:** | | * 1. **Packaging:** | | * 1. **Blinding (if applicable):** | | * 1. **Receiving, storage, dispensing and return:** | | * 1. **If proven beneficial, anticipated availability (and cost) to participants/local sites post –study:** | | FORESEEABLE RISKS AND POTENIAL BENEFITS:   1. **s and Potential Benefits** | | * 1. **Complications of study procedures:** | | * 1. **Drug side effects and toxicities/device malfunctions:** | | * 1. **Psychosocial (non-medical) risks, discomforts, inconveniences:** | | * 1. **Radiation exposure:** | | * 1. **Potential benefits to individual participant:** | | * 1. **Potential benefits to patient class, community, country, or society:** | | SAFETY ASSESSMENT: | | * 1. **Safety parameters:** | | * 1. **Definition of adverse event and serious adverse event:** | | * 1. **Adverse event (AE) reporting (method, distribution and time frame):** | | * 1. **Serious adverse event (SAE) reporting (method, distribution and time frame):** | | * 1. **AE/SAE follow-up:** | | STUDY MONITORING AND QUALITY ASSURANCE: **Quality Assurance** | | * 1. **Data and safety monitoring:** | | * 1. **Regulatory compliance auditing:** | | | | | |

Provide one copy of the following documents:

* Application for Human Research, including as applicable:
  + Appendix A: Drugs, Biologics and Devices
* Detailed Protocol
* Data collection instruments (questionnaires, etc.; do not submit case report forms)
* All written material to be provided to or meant to be seen or heard by participants, including:
  + Evaluation instruments and surveys
  + Advertisements (printed, audio, and video)
  + Recruitment materials and scripts
  + Consent documents
* If consent will not be documented in writing, a script of information to be provided orally to participants

Provide one copy of the following documents when they exist:

* Grant application
* Complete sponsor protocol
* Protocol Summary (when applicable)
* Current investigator brochure for each investigational drug
* Current package insert for each marketed drug
* Current product information for each investigational device

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| Department Chair or Supervisor Approval | | | |
| **I have reviewed this application and determined that all departmental requirements are met and that the investigator has appropriate resources to conduct the Research.** | | | |
| **Departmental Chair or Supervisor Signature** | | | Date |
| Name | **Signature** | |  |
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| Investigator Acknowledgement | | | |
| **I agree to conduct this Research in accordance with applicable regulations and the KAU Faculty of Medicine’s policies and procedures and submission of progress reports if this application is approved .** | | | |
| **Principal Investigator signature** | | Date | |
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| **Appendix A: Drugs, Biologics and Devices** | | | | | | | | |
| **List all agents being studied in the research:** | | | | | | Type | | IND # (or none or N/A) |
| Generic Name | | Brand Name | | Manufacturer | |
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| For each drug with an IND number, ensure that the application includes one of the following:   * Sponsor protocol with the IND number. * Communication from the sponsor with the IND number. * Communication from the FDA with the IND number | | | | | | | | |
| **List all devices being evaluated for safety or effectiveness or used as a comparator:** | | | | | IDE # (or none) | | Claim of an abbreviated IDE (non significant risk) | |
| Device Name | Brand Name | | Manufacturer | |  | |  | |
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| For each device with an IDE number, ensure that the application includes one of the following:   * Sponsor protocol with the IDE number. * Communication from the sponsor with the IDE number. * Communication from the FDA with the IDE number. | | | | | | | | |