Title: Atorvastatin therapy in the treatment of dyslipidemia in children with steroid sensitive nephrotic syndrome

Date : 27th January 2024

NCT number : ID not yet assigned

INTRODUCTION

Nephrotic syndrome is the most common childhood kidney disease. Nephrotic syndrome (NS) is defined by massive proteinuria & hypoalbuminemia with resulting edema & hyperlipidemia (Boyer et al. 2017). Dyslipidemia has long been recognized as a frequent metabolic abnormality in patients with nephrotic syndrome, having first been documented in 1917 (Benakappa et al. 1976). Hyperlipidemia is an important characteristic of idiopathic nephrotic syndrome in children. Abnormal lipid metabolism is common in patients with nephrotic syndrome where hypercholesterolemia with hypertriglyceridemia is seen in 90% & 98 % of cases respectively (Vaziri ND.et al 2018). Hyperlipidemia occurs because of increase hepatic synthesis of lipoprotein due to hypoalbuminemia and decreased catabolism of individual lipid fraction due to loss of lipoprotein lipase and lipoprotein lipase receptor and due to drugs used (steroid, cyclosporine, tacrolimus) in the treatment of nephrotic syndrome. Hyperlipidemia is usually observed during the active phase of the disease and disappears with resolution of proteinuria (Merouni et al 2003). Nephrotic syndrome results in deficiencies in peripheral tissue
lipoprotein lipase activity, hepatic lipase activity, and hepatic VLDL receptors, as well as increased levels of cholesteryl ester transfer protein and lipoprotein receptor related protein. These abnormalities cause reduced lipolysis of VLDL and chylomicrons, resulting in hypertriglyceridemia, increased VLDL, impaired clearance of chylomicrons, and postprandial lipemia in NS. The plasma concentrations of total cholesterol (CH), triglyceride (TG), low density lipoprotein (LDL), very low-density lipoprotein (VLDL), apolipoprotein-b and lipoprotein(a) are increased during active phase of the disease. But despite the disappearance of proteinuria, hyperlipidemic profiles were present in nearly half of nephrotic patients at remission (Me´rouani et al 2003). Persistent hyperlipidemia after remission can be found in frequent relapse nephrotic syndrome and steroid resistant nephrotic syndrome (Querfield et al 1999). Dyslipidemia is a risk factor for atherosclerosis, hence, children with NS have a higher risk for vascular disease due to atherosclerosis (Agrawal et al 2018) Therefore, children with unremitting NS have marked dyslipidemia that likely greatly increases their risk for future cardiovascular complications (Hari. P et al 2020). Dyslipidemia may also aggravate glomerulosclerosis and contribute to progression of renal injury (Hari, P et al 2018). The persistence and severity of lipid changes in serum correlates well with the duration and frequency of the relapses, even during the

remission which leads to increased risk of atherosclerosis in later life and the development of progressive renal injury (Su x et al 2015). Although nearly all patients with nephrotic syndrome experience dyslipidemia, patients who have frequent relapses or have steroid-resistant nephrotic syndrome (SRNS) are most at risk from the associated biochemical changes (Querfield et al 1999). Hence, dyslipidemia is an important modifiable risk factor, the treatment of which has become an issue, increasingly important as long-term survival among patients with nephrotic syndrome continues to improve (Warady BAet al 2015). Therapy with antihyperlipidemic agents during childhood may be of considerable benefit in the nephrotic syndrome patient population to prevent such damage from occurring (Nishi S et al 2016). Hydroxymethylglutaryl coenzyme A (HMG-CoA) reductase inhibitors (statins), the most potent cholesterol-reducing agents available, are currently the first-line pharmacologic therapy for adult hyperlipidemia in glomerular disease (KDIGO 2021 clinical practice guideline) but no such evidenced based guideline is established in case of pediatric management of dyslipidemia in nephrotic syndrome. Statins are more effective at correcting the lipid profile than use of dietary restriction of fats and cholesterol alone, in patients with glomerular disease, in particular nephrotic syndrome. (Pediatric nephrology On-The-Go 4th edition). HMG-CoA reductase catalyzes the rate-limiting step in cholesterol biosynthesis, in which HMG-CoA is converted to mevalonate. Statins act primarily in the liver where a compensatory increase in low-density lipoprotein receptor expression results in an increase in the hepatic clearance of low-density lipoprotein cholesterol (LDL-C). Accompanying this reduction in LDL-C, statins also decrease very-low-density lipoprotein cholesterol (VLDL-C) and triglyceride levels and increase high-density lipoprotein cholesterol (HDL-C) levels. Besides the lipid-lowering effect, statins have been suggested to inhibit the development of cardiovascular disease through anti-inflammatory, antioxidant, vascular endothelial function-improving, plaque-stabilizing, and platelet aggregation-inhibiting effects (Morufuji et al 2022) Taking these actions into consideration and given the significant cholesterol reduction needed with nephrotic syndrome dyslipidemia, statins appear to be a promising therapeutic option. As with other statins, atorvastatin is a competitive inhibitor of HMG-CoA reductase. Also, it is on the WHO list of essential medicines.

We therefore propose to examine, in a prospective quasi experimental study, whether administration of atorvastatin is effective in improving dyslipidemia in children with steroid sensitive nephrotic syndrome.

RATIONALE OF THE STUDY

Dyslipidemia secondary to nephrotic syndrome resulting from several pathophysiology may persist in some children both in relapse and remission. Dyslipidemia is an important modifiable risk factor that may also aggravate glomerulosclerosis and contribute to progression of renal injury. Usually, dyslipidemia resolves with disease remission in some steroid responsive patients with dietary modification. But Serum cholesterol, triglyceride and low-density lipoprotein which were elevated during active disease, may also remain elevated even after urinary remission, in some different types of steroid sensitive Nephrotic Syndrome.

Dyslipidemia plays a part in the increased rate of atherosclerosis in patients with nephrotic syndrome, which in turn increases the risks of multiple cardiovascular morbidities, including stroke, myocardial infarction and thrombosis. More importantly, dyslipidemia itself causes renal injury, which, if not interrupted, contributes to progressive CKD and, ultimately, the development of end-stage renal disease in some patients.

Many studies have been done on the outcome of statin therapy in adult nephrotic syndrome. But in the pediatric population such studies are very few. So, the proposed study was designed to see the outcome of atorvastatin therapy in children with steroid sensitive nephrotic syndrome.

RESEARCH QUESTION

Is Atorvastatin beneficial for the treatment of dyslipidemia in steroid sensitive Nephrotic Syndrome in children?

HYPOTHESIS

Atorvastatin is needed in the treatment of dyslipidemia in steroid sensitive Nephrotic Syndrome in children.

OBJECTIVES

General objective: To see the outcome of Atorvastatin therapy in children with dyslipidemia in steroid sensitive nephrotic syndrome.

Specific objective

1. To measure the serum lipid profile (total cholesterol, triglyceride, LDL, VLDL, and HDL) in nephrotic childs' of both groups.
2. To compare the serum lipid profile (total cholesterol, triglyceride, LDL, VLDL, and HDL) in nephrotic childs' of both groups.
3. To see the effectiveness of atorvastatin therapy in intervention group by comparing with control group.
4. To look for the side effects of atorvastatin in intervention group.

MATERIALS & METHODS

Study type

Quasi Experimental Study

Place of study

This study will be conducted at the department of Pediatric Nephrology & Nephrology department, National Institute of Kidney Diseases & Urology, Sher-E-Bangla Nagar, Dhaka

Period of study

The study period for this study is from December 2023 to August 2025.

Study population

Indoor and outdoor patients of different types of steroid sensitive nephrotic syndrome at Pediatric Nephrology department & Nephrology department of National Institute of Kidney Diseases.

Sampling method:

Consecutive children who fulfilled the inclusion criteria during study period will be enrolled then categorized into different groups by simple randomization.

SELECTION CRITERIA

Inclusion criteria

Children aged 8-18 years of both sexes with known case of Steroid Sensitive Nephrotic Syndrome with LDL ≥ 130 mg/dl in consecutive serum fasting lipid profile at least 1 week apart while on remission.

Exclusion criteria

- Children with previously diagnosed hyperlipidemia other than Nephrotic Syndrome.
- Children with steroid resistant nephrotic syndrome
- Children already on lipid lowering drugs
- Secondary nephrotic syndrome.
- Those parents/patients who refused to participate.

Sample size

The sample size was determined by following formula

$$n = \frac{(Z_\alpha + Z_\beta)^2 \times (\sigma_1^2 + \sigma_2^2)}{(\mu_1 - \mu_2)^2}$$

Here, n= sample size

μ_1 = 115.8 [Mean LDL of IFRNS group (Hoque et al., 2022)]

μ_2 =153.2 [Mean LDL of FRNS group (Hoque et al., 2022)]

σ_1 = 38.8 [SD of LDL of IFRNS group (Hoque et al., 2022)]

σ_2 = 43.9 [SD of LDL of FRNS group (Hoque et al., 2022)]

Z_α = 1.96 at a 95% confidence interval

Z_β = 0.85 at a 80% power

Putting the values in the above equation the sample size n is estimates as

$$n = \frac{(1.96+0.85)^2 \times (38.8^2 + 43.9^2)}{(115.8-153.2)^2} = 19.37 \approx 20$$

Sample size will be 20 in each group.

Hoque, S.S., Islam, M.A., Akter, T., Roy, R.R. and Rahman, M.H., 2022. Comparison of Lipid Profile in Different Types of Steroid Sensitive Idiopathic Relapsing Nephrotic Syndrome in Children during Active Disease and Remission. *Medicine Today*, *34*(2), pp.111-116.

METHODOLOGY OF DATA COLLECTION

This is a prospective quasi experimental study. Children aged 8-18 years with steroid sensitive nephrotic syndrome with LDL ≥ 130 mg/dl in consecutive serum fasting lipid profile at least 1 week apart, while on remission, will be enrolled based on selection criteria. Informed written consent will be taken from the parents. Ethical clearance will be obtained from the institutional ethical committee. On entry into the study a detailed history will be taken & proper physical examinations will be done. Routine investigations such as complete blood count, CRP, serum albumin, serum lipid profile, serum creatinine, Spot Urine PCR /24 hours UTP, urine routine examination and culture, X-ray chest will be done. Infection will be screened out and appropriate measures will be taken.

Patients who are eligible will be categorized for general dietary advice for nephrotic syndrome into (Group –A) and dietary advice with atorvastatin therapy (for Group- B) using a non-randomized method (odd number getting only dietary advice and even number getting dietary advice with atorvastatin). Dietary advice will be provided by dietician of NIKDU. Atorvastatin will be given according pediatric practice guidelines (0.3mg-0.5mg/kg/day ; max dose 1.6mg/kg/day) for 3 months.

Both groups will be followed up at 1 month and at 3 months from intervention. In each follow-up visit the following parameters will be observed, such as response to treatment of both groups and to see if there are any side effects of atorvastatin therapy.

The results will be documented in a predesigned data sheet for statistical analysis.

Chi-square, paired t-test and ANOVA test will be done whenever required

Relative risks, odds ratios, or hazard ratios. Pooled risk ratios (RRs) and 95 % confidence intervals (CIs) will be calculated.

Demographic variable of patient

Baseline and clinical characteristics
Gender: Male/ Female
Age
Rural/Urban

Clinical variable

Weight
Height
BMI
Temperature
Blood Pressure
Respiratory rate and chest findings
BSUA
Oedema
Ascites
Hepatomegaly
Muscle tenderness

Laboratory variable

CBC
CRP
S. creatinine
Urine R/M/E and Culture
Spot Urinary PCR/ 24 hours UTP
S. Albumin
S. Fasting Lipid Profile
Chest X ray
SGPT
RBS
CPK MB (only for intervention group)

ETHICAL IMPLICATIONS

- Ethical clearance for the study will be taken from the ethical committee of NIKDU.
- Parents of every study subject will be informed about the nature, purpose and implications of the study.
- Subjects will be assured of their confidentiality and freedom to withdraw from the study anytime.
- Written consent will be taken from all parents without any influences prior to study and without exploiting any weakness of the subjects.

QUALITY ASSURANCE

Training and piloting: Under guidance of supervisor and/co-supervisor collected data will be verified and cross-checked by supervisor and co-supervisor.

Study procedure

This will be a prospective quasi experimental study and will be conducted in the Department of Pediatric Nephrology & Nephrology Department of NIKDU, from December 2023 to August 2025. who had fulfilled inclusion criteria will be enrolled. Ethical clearance will be obtained from the institutional ethical committee of NIKDU. Quality assurance measurements will be recorded with a semi structured questionnaire. Informed written consent will be taken from the parents. All patients will be interviewed by structured questionnaire. Participants will have every right to withdraw themselves from the study at any point in time. Ethical issues will be addressed to every patient.

Protocol writing and taking ethical clearance
↓
Enrollment of patients (based on selection criteria)
↓
Semi structured data sheet to be fulfilled
↓
Physical findings & Lab information
↓
Entry of data and then analysis of data
↓
Reporting of the results

Research instruments

For data collection: Semi structured data sheet containing-

- Demography of the patient.
- Laboratory investigations.

Statistical analysis

- Qualitative variables (sex) of these studies will be expressed as percentage.
- Quantitative variable (age) will be expressed as mean ± standard deviation.
- Numerical variables will be presented as mean, median and standard deviation.
- Continuous data will be analyzed using the Mann–Whitney U test, whereas categorical data will be investigated using the chi-square test.
- Differences between the two groups at the end of 3 months will be determined using Kaplan–Meier curves. A p value of <0.05 will be considered significant.

OPERATIONAL DEFINITIONS

These are applicable for this study.

Nephrotic Syndrome (NS): NS is characterized by nephrotic range proteinuria (urinary protein creatinine ratio >2mg/mg or 3+ dipstick) and either hypoalbuminemia (serum albumin <3 g/dl) or edema (KDIGO 2021).

Remission: Protein free urine (urine protein negative or trace or <4mg/m²/hr) for 3 consecutive days (Bagga and Srivastava, 2016).

Relapse: Recurrence of nephrotic range proteinuria (urine protein 3+ or more) for 3 consecutive days. (KDIGO 2021)

Steroid Sensitive Nephrotic Syndrome: Complete remission after 4 weeks of prdenisolone or prednisolone at standard dose. (KDIGO 2021) month period. (KDIGO 2021)

Infrequent Relapse nephrotic syndrome (IFRNS): <2 relapses per 6 months within 6 months of disease onset or < 4 relapses per 12 months in any subsequent 12-

Frequent relapse nephrotic syndrome (FRNS): ≥2 relapses per 6 months within 6 months of disease onset or ≥ 4 relapses per 12 months in any subsequent 12-month period. (KDIGO 2021)

Steroid dependent nephrotic syndrome (SDNS): Occurrence of 2 consecutive relapses during therapy with prednisolone or prednisolone (either at full dose or tapering) or within 15 days of prednisolone or prednisolone discontinuation. (KDIGO 2021)

Steroid resistant nephrotic syndrome (SRNS): Lack of complete remission at 4 weeks of therapy with daily prednisolone or prednisolone at standard dose. (KDIGO 2021)

BMI: Weight in kg/Height in squared meter.

Normal BMI: 5th to 85th percentile for age and gender according to CDC growth chart.

Hyperlipidemia: An increase in one or more of the plasma lipids levels. Serum total cholesterol ≥200mg/dl, LDL cholesterol ≥130 mg/dl, triglyceride ≥130 mg/dl, and HDL >45mg/dl acceptable, 35-45 borderline, <35 low (Kwiterovich, 2008).

Dyslipidemia: is an abnormal amount of lipids (e.g.: triglycerides, cholesterol and/or fat phospholipids) in the blood. (Kwiterovich, 2008)

Hypertension: Systolic or diastolic blood pressure value above the 95th percentile for age, gender and height considered as hypertensive and Systolic or diastolic blood pressure value below the 90th percentile considered as normotensive (Bagga and Srivastava, 2016). Or parents reported previous diagnosis of hypertension by physician and taking anti-hypertensive medication.

Hyperglycemia: Random serum glucose ≥7.8 mmol/L.

Free of acute infection: No clinical sign of infection, normal body temperature, no foci of inflammation in the body, total and differential leucocyte count within normal range 4000 - 11,000/mm^3, CRP ≤10mg/L

Normal SGPT: 10 - 45IU/L

Normal CPK MB: 5- 25 IU/L

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APPENDIX - I

TIMETABLE

(Activities with time schedule)

Topic selection:	July 2023
Literature search:	Before and all through the study period
Protocol writing:	August 2023
Approval of the protocol:	December 2023
Data collection:	December 2023 to August 2025
Data processing and analysis &Thesis writing:	September 2025

APPENDIX –II

The investigations required in this study are directly related to the management of these patients. So the investigation cost will be borne by the patient or his/her relatives. The expenditure for the study is solely for operational expenses, which is as follows:

Items Cost per patients (Taka)	Total number of patients	Total cost (Taka)
CBC	40	10000
RBS	40	10000
S. creatinine	40	10000
Urine R/M/E	40	10000
Urine C/S	40	10000
S. Albumin	40	10000
S. Fasting Lipid Profile	40	80000
Urine spot protein creatinine ratio/ 24 hoursUrinary total protein	40	20000
Chest x-ray	40	10000
SGPT	40	10000
CPK MB	40	60000
Literature review through internet		5000
Printing, binding		20000
Miscellaneous		15000

Total cost: Taka 2,80,000/=

DATA COLLECTION SHEET

Title: Atorvastatin therapy in the treatment of dyslipidemia in children with Steroid Sensitive Nephrotic Syndrome

Serial No: Hospital Reg.No: Hospital Name:

Researcher:
Dr Saieef Zaman
MD (Pediatric Nephrology) Phase B
Dept. Of Pediatric Nephrology
National Institute of Kidney disease & Urology
Phone : 01766400573

Date of admission/outdoor visit ……

Date of enrollment: .....

Address: …….

Telephone/Mobile No……

Socio demographic data:

1. Name:
2. Age :
3. Sex : 1=Male, 2=Female
4. Father's name:
5. Mother's name:
6. Legal guardian's name:
7. Residence:
   1=Rural, 2= Urban 2
8. Religion:
   1= Islam, 2= Hindu, 3= Christian, 4= Others
9. Fathers occupation:
   1= Farmer, 2= Business, 3= Service ,4= Day laborer, 5= Others
10. Mothers occupation:
    1= Housewife, 2= Business, 3= Service ,4= Day laborer, 5= Others
11. Socioeconomic status (monthly income in taka):
    1=Low, 2=Lower middle , 3=Upper Middle, 4= High
12. Level of education (Father):
    1=Primary, 2=High school, 3= College & University, 4= No education
13. Level of education (Mother):
    1=Primary, 2=High school, 3= College & University, 4= No education

14)Immunization: Immunized as per EPI Schedule (1) Not immunized (2)
15)Age of onset of nephrotic syndrome:
16)Clinical diagnosis:
1= infrequent relapse, 2= frequent relapse 3=steroid dependent
17)Treatment with corticosteroid/other immunosuppressant:
1=corticosteroid,2=mycophenolatemofetil,3=tacrolimus 4=Cyclosporin, 5=others

18)History of Cardiovascular disease in family:

19) Date of starting treatment:
Dietary Advice:
Diet Advice + Atorvastatin therapy:

20) Demographic variable of patient:

Baseline and clinical characteristics
Gender: Male/ Female :
Age :
Rural/Urban:

21) Clinical variable:

Date		
Weight		
Height		
BMI		
Temperature		
Pulse		
Blood Pressure		
Respiratory rate and chest findings		
Bed Side Urine Albumin		
Oedema		
Ascites		
Others:(Hepatomegaly, Muscle Pain)		

22) Laboratory variable:

Date			
CBC	Hb% ESR TLC N L M E Platelet		
CRP			
S. creatinine			
Urine R/M/E Albumin RBC Pus cell			
Urine Culture			
Chest X ray			
Spot Urinary PCR			
S. Albumin			
S. Fasting Lipid Profile	Total cholesterol TG LDL HDL		
SGPT			
S.CK MB			
RBS			

Dr Saieef Zaman
MD (Pediatric Nephrology) Phase B
Dept. Of Pediatric Nephrology
National Institute of Kidney disease & Urology
Phone : 01766400573

Follow Up Sheet

A. Clinical F/UP

Clinical variable	1 month	3 month	6 month
Weight			
Height			
BMI			
Temperature			
Pulse			
Blood Pressure			
Respiratory rate and chest findings			
BSUA			
Oedema			
Ascites			
Others (Hepatomegaly,Muscle pain etc)			
Date & signature			

Dr Saieef Zaman
MD (Pediatric Nephrology) Phase B
Dept. Of Pediatric Nephrology
National Institute of Kidney disease & Urology
Phone : 01766400573

B, **Laboratory F/UP**

Laboratory variable			1 month		3 month		6 month	
CBC Hb% ESR TLC N L M E Platelet								
CRP								
S. Creatinine								
Urine R/M/E Albumin RBC Pus cell								
Urine culture								
Chest X ray								
Spot Urinary PCR								
S. Albumin								
S.Fasting	T.Cholesterol	TG						
Lipid Profile	LDL	HDL						
SGPT.								
S CK MB								
RBS								
Date & Signature								

Dr Saieef Zaman
MD (Pediatric Nephrology) Phase B
Dept. Of Pediatric Nephrology
National Institute of Kidney disease & Urology
Phone : 01766400573

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Atorvastatin therapy in the treatment of dyslipidemia in children with Steroid Sensitive Nephrotic Syndrome

Investigator: Dr. Saieef Zaman **Phone: 01766400573**

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GB M‡elbvq Ask MÖnb Kiv wKsev bv Kiv‡Z Avcbvi ev”Pvi †b‡d«vwUK wmb‡Wªvg Gi wPwKrmvi †Kvb ZviZg¨ n‡e bv| Ask MÖnb Kivi ci †h †Kvb mgq Avcbx Avcbvi ev”Pv‡K M‡elbv †_‡K mwi‡q wb‡Z cvi‡eb|

LiP:

GB M‡elbvq Ask MÖn‡bi Rb¨ Avcbvi evowZ †Kvb LiP †bB|

‡MvcbxqZv:

M‡elbv PjvKvjxb I cieZx©‡Z mgq Z_¨ K‡Vvi fv‡e †Mvcb Kiv n‡e| Avcbvi ev”Pvi Rb¨ GK M‡elbv PjvKvjxb I cieZx©‡Z mgq Z_¨ K‡Vvi fv‡e †Mvcb Kiv n‡e| Avcbvi ev”Pvi Rb¨ GKwU AvBwW †`Iqv n‡e| Avcbvi AvBwW b¤^i m¤^wjZ me ai‡bi KvMR cÎ Avcbvi bvg, wVKvbv ewm‡q Awd‡mi dvBwjs †Kwe‡b‡U Zvjve× _vK‡e| e¨w³MZ welqvw` Z_¨ we‡køl‡b, cÖwZ‡e`b •Zix cÖKvkbvi Kv‡R e¨envi Kiv n‡e Ges M‡elbvi cixÿK e¨ZxZ Kv‡iv Kv‡Q cÖKvk Kiv n‡e bv| d‡j Avcbvi Z_¨ †KD Rvb‡Z cvi‡e bv|

‡¯^”Qv g~jK Ask MÖnb:

GB M‡elbvq Avcbvi ev”PviAsk MÖnb m¤ú~Y© †¯^”Qvg~jK| Avcwb M‡elbvq Ask MÖn‡b A¯^xK…wZ Rvbv‡Z cv‡ib A_ev M‡elbv PjvKvjxb †h †Kvb mgq M‡elbv †_‡K Avcbvi ev”Pv‡K cÖZ¨vnvi K‡i wb‡Z cv‡ib| Zv‡Z Avcbvi wPwKrmvi ZviZg¨ n‡ebv| GB di‡g ¯^vÿi Ki‡j Avcbvi ev”Pvi AvBbMZ †Kvb AwaKvi Le© n‡e bv|

mgqt

GB M‡elbvq Avcbvi 6 □□□ □□□ □□□□□ □□□ □ □□□□□□ □□□□□□□□□□ □□, □□□ 1, 3 □□ □□□ □□ □□□□□ □□□□ □□□□

cÖkœvejxt

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m¤§wZ ¯^xKv‡ivw³t

Avwg M‡elYvq wb‡qvwRZ wPwKrm‡Ki mv‡_ (whwb Avgvi ev”Pvi kvixwiK cixÿv Ki‡eb) GB M‡elYv wb‡q Av‡jvPbvq mš‘wó cÖKvk KiwQ| Avwg GUv ey‡SwQ †h, M‡elYvq Ask MÖnY †¯^”Qv g~jK Ges Avwg †h †Kvb mgq †Kvb eva¨evaKZv QvovB M‡elYv †_‡K Avgvi ev”Pv‡K weiZ ivL‡Z cvwi| Avwg Dc‡iv³ welq,‡jv c‡owQ / Avgvi m¤§‡L cwVZ n‡q‡Q Ges †¯^”Qvq M‡elYvq Ask MÖnY Ki‡Z m¤§wZÁvcb KiwQ|

M‡el‡Ki ¯^vÿi t ZvwiLt

bvgt

Ask MÖnbKvixi ¯^vÿit ZvwiLt

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Awffve‡Ki ¯^vÿi/e„×v½ywji Qvct ZvwiLt

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AewnZ m¤§wZcÎ/Assent Form

Atorvastatin therapy in the treatment of dyslipidemia in children with Steroid Sensitive Nephrotic Syndrome

Investigator: Dr. Saieef Zaman Phone: 01766400573

GB m¤§wZc‡Îi D‡Ïk¨ nj Avcbv‡K cÖ‡qvRbxq Z_¨ cÖ`vbKiv, †h Z_¨,‡jv Avcbv‡K wm×všÍ wb‡Z mvnvh¨ Ki‡e, Avcwb GB M‡elYvq AskMªnb Ki‡eb wKbv?

M‡el‡Ki cwiwPwZt

Avwg Wvt mvCd Rvgvb, b¨vkbvj Bbw÷wUDUAe wKWwb wWwR‡RR GÛ BD‡ivjwR‡Z wkï wKWbx wefv‡Mi Gg.wW ‡iwm‡WwÝ, ‡dBR-we Gi wPwKrmK wn‡m‡e Kg©iZ AvwQ| Avwg wkï ‡b‡d«vwUK wmb‡W«vg ‡iv‡Mi Kvi‡Y i‡³ ‡Kv‡j‡÷‡iji cwigvY ‡ewk _vK‡j, Zvi wPwKrmvi Dci M‡elYv KiwQ| Avwg Avcbv‡K GB m¤ú‡K© c«‡qvRbxq Z_¨ c«`vb K‡i GB M‡elYvq AskM«n‡bi Avn&evb KiwQ|

f~wgKv:

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D‡Ïk¨ jÿ¨ :

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M‡elbvi SzwK:

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LiP:

GB M‡elbvq Ask MÖn‡bi Rb¨ Avcbvi evowZ †Kvb LiP †bB|

‡MvcbxqZv:

M‡elbv PjvKvjxb I cieZx©‡Z mgq Z_¨ K‡Vvi fv‡e †Mvcb Kiv n‡e| Avcbvi Rb¨ GK M‡elbv PjvKvjxb I cieZx©‡Z mgq Z_¨ K‡Vvi fv‡e †Mvcb Kiv n‡e| Avcbvi Rb¨ GKwU AvBwW †`Iqv n‡e| Avcbvi AvBwW b¤^i m¤^wjZ me ai‡bi KvMR cÎ Avcbvi bvg, wVKvbv ewm‡q Awd‡mi dvBwjs †Kwe‡b‡U Zvjve× _vK‡e| e¨w³MZ welqvw` Z_¨ we‡køl‡b, cÖwZ‡e`b •Zix cÖKvkbvi Kv‡R e¨envi Kiv n‡e Ges M‡elbvi cixÿK e¨ZxZ Kv‡iv Kv‡Q cÖKvk Kiv n‡e bv| d‡j Avcbvi Z_¨ †KD Rvb‡Z cvi‡e bv|

‡¯^"Qv g~jK Ask MÖnb:

GB M‡elbvq Avcbvi Ask MÖnb m¤ú~Y© †¯^"Qvg~jK| Avcwb M‡elbvq Ask MÖn‡b A¯^xK…wZ Rvbv‡Z cv‡ib A_ev M‡elbv PjvKvjxb †h †Kvb mgq M‡elbv †_‡K □□□□ cÖZ¨vnvi K‡i wb‡Z cv‡ib| Zv‡Z Avcbvi wPwKrmvi ZviZg¨ n‡ebv| GB di‡g ¯^vÿi Ki‡j Avcbvi AvBbMZ †Kvb AwaKvi Le© n‡e bv|

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GB M‡elbvq Avcbvi 6 □□□ □□□ □□□□□ □□□ □ □□□□□□□□□□ □□, □□□ 1, 3 □□ □□□ □□ □□□□□ □□□□ □□□□

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hw` Avcbvi †Kvb cÖkœ _v‡K Z‡e `qv K‡i wRÁvmv Ki‡eb| Avwg Avcbvi DËi cÖ`vb Kivi h_vmva¨ †Póv Ki‡ev| hw` fwel¨‡Z Avcbvi ‡Kvb □□□□□□□□ D‡`«K nq Zvn‡j M‡elYviZ □□□ □□□□ □□□□□, □□□□ □□□□□ wefvM, □□□□□- 628, □□□□□□□□ □□□□□□□□□□ □□ □□□□□ □□□□□□□ □□□□ □□□□□□□ □‡hvMv‡hvM Ki‡Z cvi‡eb □Avgvi ‡gvevBj bv¤^vi nj 01766400573□

m¤§wZ ¯^xKv‡ivw³t

Avwg M‡elYvq wb‡qvwRZ wPwKrm‡Ki mv‡_ (whwb Avgvi kvixwiK cixÿv Ki‡eb) GB M‡elYv wb‡q Av‡jvPbvq mš‘wó cÖKvk KiwQ| Avwg GUv ey‡SwQ †h, M‡elYvq Ask MÖnY †¯^"Qv g~jK Ges Avwg †h †Kvb mgq †Kvb eva¨evaKZv QvovB M‡elYv †_‡K weiZ ivL‡Z cvwi| Avwg Dc‡iv³ welq‚‡jv c‡owQ / Avgvi m¤§‡L cwVZ n‡q‡Q Ges †¯^"Qvq M‡elYvq Ask MÖnY Ki‡Z m¤§wZÁvcb KiwQ|

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Ask MÖnbKvixi ¯^vÿit ZvwiLt

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INFORMED CONSENT FORM IN ENGLISH

TITLE: Atorvastatin therapy in the treatment of dyslipidemia in children with Steroid Sensitive Nephrotic Syndrome

Investigator:Dr Saieef Zaman Phn no: 01766400573

ID no. of the participant:

The aim of this consent form is to give you the information that will help you to make decision whether you will participate in research.

About the Researcher:

I am Dr.Saieef Zaman, working as a doctor of MD phase B resident in the department of Pediatric Nephrology, National Institute of Kidney Diseases and Urology. I am researching on topics related to the treatment of dyslipidemia in children with Steroid Sensitive Nephrotic Syndrome. I will provide you necessary information and invite you to participate in this study. The purpose of this consent form is to give you relevant information which will help you whether you will participate in this research or not.

Introduction:

Nephrotic syndrome is a curable disease Hypercholesterolemia is one of the complications of this disease. For this reason, these children are more susceptible to developing atherosclerosis.

Atherosclerosis is one of the major risks for developing cardiovascular diseases. Also, these patients may develop glomerulosclerosis ultimately ending in CKD.

Purpose of the study:

Aim of the study is to measure the serum Fasting lipid profile in different types of Steroid Sensitive Nephrotic Syndrome in Children and manage it either by dietary intervention or by dietary intervention and atorvastatin to find out which is better. This study will be held in the Pediatric Nephrology/Nephrology Department. If you give your consent to participate in this study, then I will take some information about your child.

Risk of the study:

There is low risk to participate in this study.

Advantages in participating in this study:

Your child will benefit if they participate in this study. We will be able to know whether your child is developing increased amounts of lipid in the blood as it is a common side effect of the disease and appropriately manage it so no further complications arise from this condition. You can withdraw your child at any time from this study.

Alternative:

The normal treatment of your child shall proceed as per general treatment procedure of the hospital, even if your child do not participate in the research.

Compensation for the study: There is no excess cost in participating in this study.

Confidentiality:

In the duration of the study, your information will not be disclosed. We will give an ID to your child. Your file containing all information will be secured. Except the researcher and people related to research, this information will not be disclosed to others.

Rights as participants:

You can actively participate in this study. You can withdraw your child at any time. . If you participate in this study this will be fruitful for your child. No rights will be hampered to participate in this study.

Time Period:

The research will take 6 months of your time. Your child will be followed up at 1, 3 month & 6 month after participation.

Questions or problem:

You can ask me any question any time during this study. I will try my best to give an answer. In future, if any questions arise, please contact me by asking for Dr Saieef Zaman in Room no 628, Dept of Pediatric Nephrology, National Institute of Kidney Disease & Urology. My phone no is 01766400573.

Informed consent:

I have been informed regarding this study. I understand that I can actively participate in this study and can withdraw my child at any time. All the above things are explained in front of me. I give my consent to participate in this study.

Signature of investigator: **Date:** **Name:**

Signature of guardian: **Date:** **Name:**

Signature (Participant): **Date:** **Name:**

Signature (Witness to consent): **Date:** **Name:**

INFORMED ASSENT FORM IN ENGLISH

TITLE: Atorvastatin therapy in the treatment of dyslipidemia in children with Steroid Sensitive Nephrotic Syndrome

Investigator:Dr Saieef Zaman **Phn no: 01766400573**

ID no. of the participant:

The aim of this assent form is to give you the information that will help you to make decision whether you will participate in research.

About the Researcher:

I am Dr.Saieef Zaman, working as a doctor of MD phase B resident in the department of Pediatric Nephrology, National Institute of Kidney Diseases and Urology. I am researching on topics related to the treatment of dyslipidemia in children with Steroid Sensitive Nephrotic Syndrome. I will provide you necessary information and invite you to participate in this study. The purpose of this assent form is to give you relevant information which will help you whether you will participate in this research or not.

Introduction:

Nephrotic syndrome is a curable disease Dyslipidaemia is one of the complications of this disease. For this reason, these children are more susceptible to developing atherosclerosis.

Atherosclerosis is one of the major risks for developing cardiovascular diseases. Also, these patients may develop glomerulosclerosis ultimately ending in CKD.

Purpose of the study:

Aim of the study is to measure the serum Fasting lipid profile in different types of Steroid Sensitive Nephrotic Syndrome in Children and manage it either by dietary intervention or by dietary intervention and atorvastatin to find out which is better. This study will be held in the Pediatric Nephrology. If you give your consent to participate in this study, then I will take some information about you.

Risk of the study:

There is low risk to participate in this study.

Advantages in participating in this study:

You will benefit if you participate in this study. We will be able to know whether you are developing increased amounts of lipid in the blood as it is a common side effect of the disease and appropriately manage it so no further complications arise from this condition. You can withdraw yourself at any time from this study.

Alternative:

The normal treatment of yourself shall proceed as per general treatment procedure of the hospital, even if you do not participate in the research.

Compensation for the study: There is no excess cost in participating in this study.

Confidentiality:

In the duration of the study, your information will not be disclosed. We will give an ID to you. Your file containing all information will be secured. Except the researcher and people related to research, this information will not be disclosed to others.

Rights as participants:

You can actively participate in this study. You can withdraw yourself at any time. . If you participate in this study this will be fruitful for you. No rights will be hampered to participate in this study.

Time Period:

The research will take 6 months of your time. Your will be followed up at 1,3 month & 6 month after participation.

Questions or problem:

You can ask me any question any time during this study. I will try my best to give an answer. In future, if any questions arise, please contact me by asking for Dr Saieef Zaman in Room no 628, Dept of Pediatric Nephrology, National Institute of Kidney Disease & Urology. My phone no is 01766400573.

Informed consent:

I have been informed regarding this study. I understand that I can actively participate in this study and can withdraw myself at any time. All the above things are explained in front of me. I give my consent to participate in this study.

Signature of investigator: **Date:** **Name:**

Signature (Participant): **Date:** **Name:**

Signature (Witness to consent): **Date:** **Name:**

INFORMED CONSENT FORM FOR SUBJECTS

Title of research study: Atorvastatin therapy in treatment of dyslipidemia in children with Steroid Sensitive Nephrotic Syndrome

Principle investigator:
Dr. Saieef Zaman
MD (Paediatric Nephrology) Phase B
Department Of Pediatric Nephrology
National Institute of Kidney Disease & Urology
Phone : 01515682602

ID no. of the participant:

- I consent to participate in the research named above, the particulars of which including details of data sheet have been explained to me
- I authorize the researcher to use with me the interviews and to fulfill the data sheet acknowledging that:
    1. The possible effects of the interviews and data sheet have been explained to me to my satisfaction
    2. I have been informed that I am free to withdraw from the research at any time without explanation or prejudice and to withdraw any unprocessed data previously supplied
    3. The project is for the purpose of research

4. I have been informed that the confidentiality of the information I provide will be safeguarded subject to any legal requirements
5. I have been informed regarding the interviews. I have also been informed that because of the number of people to be interviewed in small; it is possible that someone may still be able to identify me on the basis of any references to personal information that might allow someone to guess my identity. However, I will be referred by pseudonym or identified by a different name in any publications arising from the research.

Signature (Participant) Date

Signature (Witness to consent) Date